SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: GORE® TAG® Thoracic Branch Endoprosthesis

Procode: MIH

Applicant's Name and Address: W. L. Gore & Associates, Inc.
3450 W. Kiltie
Lane
Flagstaff, AZ
86005, USA

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P210032

Date of FDA Notice of Approval: May 13, 2022

Priority Review: Granted priority review status on July 17, 2015 because the device is intended to treat a potentially life threatening disease and because of reasonable expectation that the device represents a breakthrough technology with the potential to provide a clinically meaningful advantage over existing legally marketed technology, offers significant, clinically meaningful advantages over existing legally marketed alternatives and the availability of the device is in the best interest of patients.

II. INDICATIONS FOR USE

The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and have:

- Adequate iliac/femoral access
- Proximal Aortic Landing Zones:
    - For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified, or heavily thrombosed
    - For Dissection Patients: Primary entry tear must be distal to

the left subclavian artery and the proximal extent of the landing zone must not be dissected

- Aortic inner diameter range 16-42 mm
- Proximal segment length (length from distal edge of left subclavian artery to mid left common carotid ostium) of at least 2.0-4.0 cm, depending on Aortic Component selection
- Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15–36 mm, depending on Aortic Component selection
- For patients with prior ascending aorta or aortic arch repair with a surgical graft: at least 2 cm landing zone proximal to the distal anastomosis

- Left Subclavian Landing Zone:
  - Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length)
  - Left subclavian artery inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected
  - Left subclavian artery minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected
- Distal Landing Zone (Isolated Lesion Patients only)
  - Outer curve length must be ≥ 2 cm proximal to celiac artery
  - Aortic inner diameter range 16-42 mm
  - Non aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone
  - Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft

III. CONTRAINDICATIONS

The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials
- Patients who have a condition that threatens to infect the graft
- Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) Type II

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE® TAG® Thoracic Branch Endoprosthesis Device labeling.

V. DEVICE DESCRIPTION

The GORE® TAG® Thoracic Branch Endoprosthesis provides endovascular repair of pathologies of the descending thoracic aorta requiring a proximal landing zone including the left subclavian artery. The GORE® TAG® Thoracic Branch Endoprosthesis is a modular device consisting of the Aortic Component (AC), the Side Branch (SB) Component, and an optional Aortic Extender (AE), as shown in **Figure 1,** and their respective delivery systems. These components may be used together as a stand-alone device or in conjunction with the GORE® TAG® Conformable Thoracic Endoprosthesis (P040043) to accommodate the intended treatment site.

Each component of the endoprosthesis consists of an ePTFE/FEP graft supported over its entire length by a nitinol wire frame (stent). Radiopaque gold bands are embedded in the graft material for device imaging. For delivery, all device components are constrained on the leading end of a delivery catheter compatible with 0.035" guidewires and are delivered through a single distal access site. All device components are intended to be delivered through an appropriately sized GORE® DrySeal Flex Sheath family of devices.

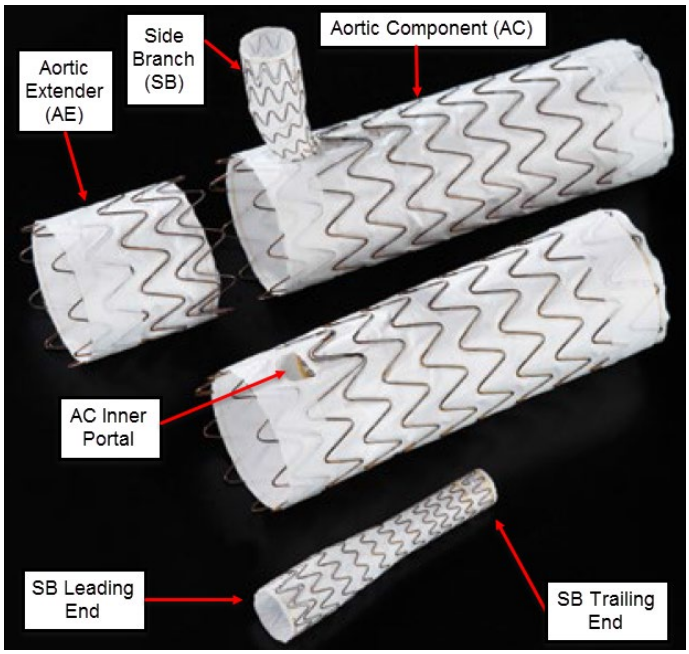

Figure 1: GORE® TAG® Thoracic Branch Endoprosthesis System and Key Features

Aortic Component (AC)

The Aortic Component (see **Figure 2**) incorporates an internal portal that opens to the outer device surface, allowing for seal and fixation of the SB Component. Embedded in both ends of the Aortic Component and the internal portal are radiopaque gold bands that provide radiographic visibility. The leading end of the endoprosthesis consists of partially uncovered stent apices, while the trailing end of the stent is in line with the graft material.

This component is mounted onto a catheter delivery system for delivery from a distal access site over a primary aortic guidewire. A Removable Guidewire Tube is provided to facilitate loading of the constrained device over a secondary branch guidewire that is pre-positioned from the distal access site to the left subclavian artery (LSA). The constrained profile on the delivery catheter ranges from 20 to 26 Fr.

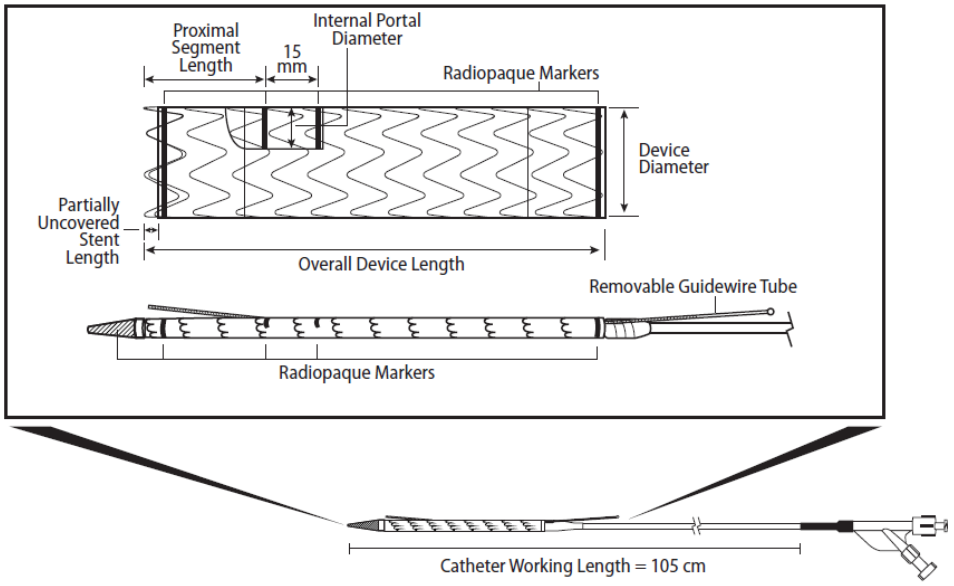

Figure 2: Aortic Component and Aortic Component Delivery System

Side Branch Component (SB)

The SB Component (see **Figure 3**) includes the CBAS® Heparin Surface which consists of stable, covalent, end-point attached heparin of porcine origin. A radiopaque gold band is embedded in the graft material at each end of the device. A third embedded radiopaque band is located 5 mm from the trailing end of the device. This inner radiopaque marker facilitates alignment of the SB Component with the Aortic Component internal portal. The SB Component is mounted onto a catheter delivery system and constrained by a deployment sleeve. The SB Component should be selected such that the diameter of the trailing portion of the graft is the same as the portal diameter of the chosen Aortic Component. The diameter of the leading portion of the SB Component should be selected such that it is compatible with the branch vessel diameter.

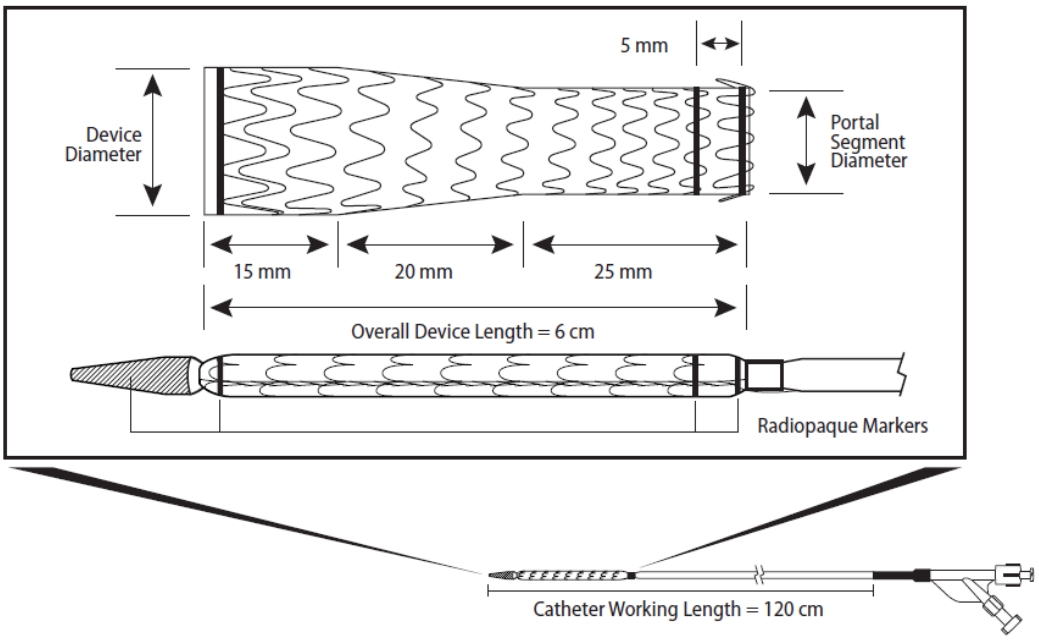

Figure 3: Side Branch (SB) Component and SB Component Delivery System

Aortic Extender (AE)

The Aortic Extender (see **Figure 4**) is a short, tubular device with radiopaque gold bands at each end for radiographic visibility. Both the leading and trailing ends consist of partially uncovered stent apices. This device is intended to be used to improve sealing of the Aortic Component and/or add seal length proximally within the aorta, if necessary. The compressed profile of these devices on the delivery catheter ranges from 20 to 26Fr. The device is mounted onto a catheter delivery system. A longitudinal radiopaque marker is embedded in the deployment sleeve to allow visualization during delivery catheter withdrawal.

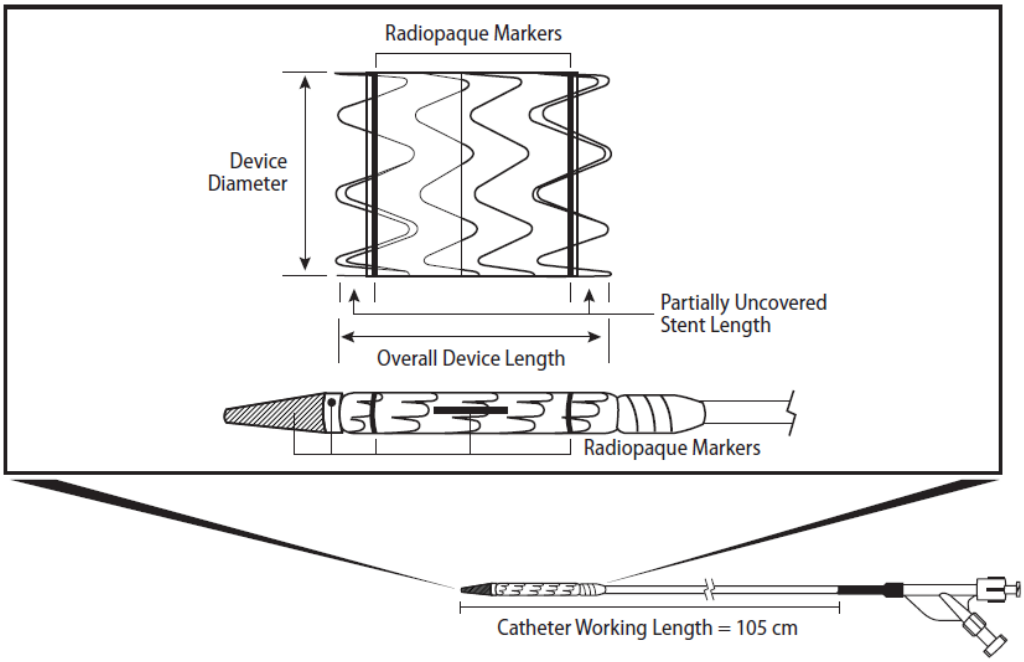

Figure 4: Aortic Extender (AE) Component and AE Component Delivery System

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery including:

- Medical management
- Open surgical repair
- Thoracic endovascular aortic repair (TEVAR) using other endovascular devices
- Hybrid surgery with TEVAR

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with their physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The GORE® TAG® Thoracic Branch Endoprosthesis has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

Table 1: List of Potential Adverse Effects

access, delivery and deployment events (e.g. access failure; deployment difficulties/failures; failure to deliver the stent graft; and insertion or removal difficulty),	fever and localized inflammation,
adynamic ileus,	fistula (e.g., aortoenteric, arteriovenous, aortoesophogeal, aortobronchial),
allergic reaction (to contrast, anti-platelet therapy, stent graft material),	genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection),
amputation,	hematoma,
anesthetic complications,	heparin-induced thrombocytopenia (HIT), infection (e.g., aortic, device, or access sites),
aortic expansion,	lymphocele / lymph fistula,
aortic rupture,	myocardial infarction,
angina,	neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis),
atelectasis / pneumonia,	nerve injury,
bleeding (procedural and post-treatment),	peripheral malperfusion or ischemia,
bowel complications (e.g., ileus, transient ischemia, infarction, necrosis),	persistent false lumen flow,
branch vessel occlusion or obstruction,	post-implant syndrome,
cardiac complications (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension),	prosthesis dilatation / rupture,
catheter breakage,	prosthetic thrombosis,
change in mental status,	pseudoaneurysm,
coagulopathy,	pulmonary complications (e.g., pneumonia, respiratory failure), pulmonary embolism,
contrast toxicity,	radiation injury,
death,	renal complications (e.g., artery occlusion, contrast toxicity, insufficiency, failure),
dissection, perforation, or rupture of the aortic vessel and / or surrounding vasculature,	reoperation,
edema (e.g., leg),	stenosis,
embolism (micro and macro) with transient	surgical conversion,

or permanent ischemia,	
endoleak,	thrombosis,
endoprosthesis: collapse, improper placement; incomplete deployment; migration; material failure; occlusion; infection; stent fracture; dilatation; perigraft flow,	transient ischemic attack,
erectile dysfunction,	vascular spasm,
erosion,	vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture),
extension of dissection,	wound (e.g., infection, dehiscence)
femoral neuropathy	fever and localized inflammation,

For the specific adverse events that occurred in the clinical study, see **Section X**.

IX. SUMMARY OF NONCLINICAL STUDIES

Nonclinical studies were completed to evaluate the GORE® TAG® Thoracic Branch Endoprosthesis including non-clinical bench testing, biocompatibility, sterilization, packaging, shelf-life, and animal studies. These are described in detail in the following sections.

A. *In Vitro* Engineering Testing

In vitro bench testing to support the GORE® TAG® Thoracic Branch Endoprosthesis is summarized in **Table 2**. It was developed based on the device risk assessment and is consistent with *FDA's Guidance Document Non-Clinical Tests and Recommended Labeling of Intravascular Stents and Associated Delivery Systems*, April 18, 2010, its addendum, *Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems*, August 18, 2015, and BS EN ISO 25539-1.

Table 2: Summary of In Vitro Test Results

Test	Test Purpose	Acceptance Criteria	Results
Endoprosthesis System (Aortic Component (AC), Aortic Extender (AE) and Side Branch (SB))			
Post-Deployment Inspections*	This test evaluates various post deployment inspections including, general visual, device integrity, contamination, dimensional inspection.	**AC/AE/SB:** The GORE® TAG® Thoracic Branch Endoprosthesis system components must meet required inspections (including measurement of length, inner diameter, and portal to leading end stent length (AC)) and be free of damage (e.g., broken struts, delamination, obstructions to the lumen) or unacceptable contamination post-deployment.	PASS

Test	Test Purpose	Acceptance Criteria	Results
Deployment Reliability*	This test is to evaluate the deployment reliability of the device in a clinically relevant anatomical model.	**AC/AE/SB:** Deployment success is the ability of the deployment system to: • Reliably access the treatment site • Reliably deploy the endoprosthesis • Reliably withdraw the delivery catheter through the deployed device and remove from the patient. The device must have acceptable introducer sheath compatibility, pushability and trackability, torqueability, device expansion, deployment force (AC and AE ≤ 7.0 lbs; SB ≤ 5.0 lbs), removal of deployment line system, catheter extraction, and balloon compatibility.	PASS
Deployment Accuracy	This test evaluates the ability of the device to deploy accurately at the intended deployment site during simulated in-vitro test conditions. Deployment accuracy is the ability of the device to accurately deploy at its target (intended) location.	**AC/AE/SB:** The difference between the intended in-vitro deployment location (target) in the appropriate model and the actual deployed location must be within ± 5 mm. Deployment accuracy of the SB and Extender components applies to the proximal and distal target locations. Deployment accuracy of the Aortic Component only applies to the proximal target location. The Aortic Component portal must intersect the ostium of the intended branch vessel. The criterion for ostium intersection is the ability to access the branch with the SB component.	PASS
Radiopacity	This test evaluates the radiopacity of the endoprosthesis system.	**AC/AE/SB**: The loaded endoprosthesis and delivery catheter must demonstrate sufficient radiopacity for clinical use. AE sleeve radiopaque marker: the sleeve of the AE shall have a radiopaque marker for identification during catheter removal post deployment. AE Olive radiopaque marker: the leading olive of the AE shall have a radiopaque marker to facilitate rotational positioning of the AE prior to deployment. Leading olive radiopacity: the leading olive of the AC, AE, and SB shall be radiopaque to identify the leading end of the delivery system.	PASS

Test	Test Purpose	Acceptance Criteria	Results
Modular Component Compatibility	This test evaluates device shortening, dislodgement, and modular separation due to deployment of additional modular devices.	**AC/AE/SB:** The Aortic Component must demonstrate acceptable modular compatibility with the Aortic Extender and the Side Branch component. Compatibility must also be demonstrated for configurations that include both GORE® TAG® Conformable Thoracic Endoprosthesis and TAG® Devices.	PASS
Catheter Sleeve Attachment Strength*	This test evaluates the attachment strength of the sleeve to the delivery catheter.	**AC/AE:** The tensile force required to separate the sleeve from the AC and AE catheter transition shall be ≥ 2.25 lbs.	PASS
Docking Separation Force	This test evaluates the force required to separate components within an endoprosthesis system.	**AC/SB:** The mean force to separate the SB component from the AC shall be greater than or equal to the mean separation force between the GORE® EXCLUDER® trunk and contralateral limb devices.	PASS
Particulate Evaluation	This test evaluates the particle counts expressed from simulated device use and provide a particle composition analysis.	**SB:** The loaded SB device must not release a clinically relevant amount of particulates.	PASS
Sewn Sleeve Function*	This test evaluates the ability of the sewn sleeve to constrain, torque, and deploy the device, and be removed with the catheter (AC and AE) in an anatomical model.	**AC/AE/SB**: The sewn sleeve must constrain the device with an outer diameter capable of being passed through the introducer sheath. The sewn sleeve must prevent premature deployment of the device when protected by the packaging sheath. After removal of the packaging sheath, the sewn sleeve must also be capable of fully opening at the time of clinical deployment. For the AC and SB components, the sleeve is secured to the stent-graft and remains implanted between the endoprosthesis and the vessel wall. The AC torque sleeve and the AE sleeve shall be secured to the delivery catheter and removed with the catheter following deployment. The AC torque sleeve and AE sleeve must couple the device to the catheter to facilitate device torquing pre-deployment.	PASS
Deployment Lumen Patency	This test evaluates the patency of the deployment line lumen.	**AC/AE/SB:** The deployment line lumen must allow passage of the deployment line(s).	PASS

Test	Test Purpose	Acceptance Criteria	Results
Acute Angle Access	This test evaluates the ability of the loaded SB to access the branch vessel in a tortuous simulated use environment.	**SB:** The SB shall track through the portal of a deployed AC device without sustaining visible damage in order to treat branch vessel angles.	PASS
Stent Graft			
Nitinol Material Analysis	This test evaluates the chemical elements present in the bulk and on the surface of the wire and examines the wire surface for contamination and/or defects.	**AC/AE/SB**: Chemically analyze and quantify the elements present in the bulk and on the surface of the wire. Examine the wire surface for contamination and/or defects. The wire surface must be adequately free of anomalies or contaminants under examination with SEM. Anomalies would include large pits or cracks on the wire surface.	PASS**
Nitinol Corrosion	This test evaluates the corrosion resistance of the endoprosthesis.	**AC/AE/SB**: Characterize the corrosion resistance of the Nitinol wire used to wind the stent. Results must be comparable to an appropriate predicate device.	Characterization **
Nickel Leachability	This test evaluates the nickel leachability of the device.	**AC/AE/SB**: The results from the worst case configuration, one TBE 53 mm x 20 cm Aortic Component (AC), one 12 mm x 20 mm Side Branch (SB), one 53 mm Aortic Extender (AE), and three 45 mm x 20 cm CTAG devices, must be less than or equal to the acute nickel limit of 290 µg/day during the first 24 hours and chronic nickel limit of 29 µg/day during the duration of the 60 day testing.	PASS
Thermo-mechanical Properties	This test evaluates the thermo-mechanical properties of the device.	**AC/AE/SB:** When deployed at 37 +/- 2°C, the device must open without excessive invagination or any unacceptable obstruction to the flow in order to confirm the superelastic property of the Nitinol material in a final device configuration. Excessive invagination is defined as infolding of the stent frame or infolding of the graft material beyond that expected in the maximum oversizing condition for the respective device size.	PASS

Test	Test Purpose	Acceptance Criteria	Results
Radial Outward Force	This test evaluates the radial outward force of the GORE® TAG® Thoracic Branch Endoprosthesis.	**AC/AE:** For each device diameter, radial force of the AC and AE must be comparable to that of the GORE® TAG® Conformable Thoracic Stent Graft. **SB:** Leading End Radial Force: The radial force of the leading end of the SB must be comparable to that of the minimum GORE® TAG® Conformable Thoracic Stent Graft radial force.	PASS
Durability Testing – Pulsatile Fatigue	This test evaluates durability through accelerated testing. Finite Element Analysis was used to determine the strains present in the wire stent structure under specific loading conditions for each size.	**AC/AE/SB:** The GORE® TAG® Thoracic Branch Endoprosthesis components must withstand simulated physiologic pulsatile loading for ten years without wire fractures, failure of the graft material, or failure of the graft material/Nitinol endoprosthesis composite that would compromise device function. Devices were evaluated in single and overlapped configurations.	PASS
Durability Testing – Aortic Bending Fatigue	This test evaluates durability through accelerated testing.	**AC:** The Aortic Component shall be evaluated in accelerated alternating-bending testing motion in a modular configuration. Wire fractures and/or ePTFE wear shall be equivalent to or better than the GORE® TAG® Conformable Thoracic Endoprosthesis device design.	PASS
Durability Testing – Side Branch Bending Fatigue	This test evaluates durability through accelerated testing.	**SB:** The SB device was evaluated in clinically relevant accelerated alternating-bending testing in a modular configuration with the Aortic component. The rate of wire fractures and/or ePTFE wear to the SB shall be better than state-of-the-art arch repair therapies and equivalent to or better than the GORE® TAG® Device design. The Aortic component portal was also evaluated for wire fractures and/or ePTFE wear. The results were interpreted with respect to GORE® TAG® Device historical clinical performance and expected clinical use.	PASS
MRI Safety and Compatibility	This test evaluates the safety of the device in an MR environment using 1.5 and 3.0 Tesla magnetic fields.	**AC/AE/SB:** The endoprosthesis shall not present an additional hazard or risk when implanted in a patient undergoing a MRI procedure or who may be present in a MRI environment of $\leq$ 3.0 Tesla. The device may affect MRI quality depending on the pulse sequence that is used and the imaging area of interest.	PASS

Test	Test Purpose	Acceptance Criteria	Results
Sealing	This test evaluates the ability of the stent-graft to seal an aneurysm in a simulated use environment.	**AC/AE/SB**: The overall rate of fluid loss, due to the sealing of the device and the water permeability of the graft material, shall be no worse than the amount of fluid lost through the GORE® TAG® Thoracic Endoprosthesis Device design.	PASS
Acute Anchoring	This test evaluates the ability of the device to remain at the target deployment location over time or with increased flow velocity.	**AC/AE/SB**: Migration of the leading and trailing ends of the device must be ≤ 5 mm.	PASS
Compression Resistance	This test evaluates the compression resistance of the device in a simulated use environment.	**AC**: The device must be resistant to compression when subjected to increased physiologically relevant pulsatile flow rates in an appropriate *in vitro* model.	PASS
Conformability	This test evaluates the ability of the device to conform in a specific anatomy. Conformance is defined as the minimum amount of surface contact between the graft material and an inner curve of a transection model that is acceptable to maintain compression resistance when subjected to increased physiologically relevant pulsatile flow rates.	**AC**: The device must conform to the inner curve of a transection model when deployed under simulated physiological flow rates.	PASS

Test	Test Purpose	Acceptance Criteria	Results
Bend Radius	This test evaluates the minimum radius that the endovascular prosthesis can bend without kinking. Bend radius is defined as the minimum radius at which the device does not kink.	**AC/AE**: The allowable bend radius must be ≤ 12.6 mm. **SB**: The SB bend radius must be ≤ 2.5 mm.	PASS
Heparin Activity	This test evaluates the heparin activity of the side branch.	**SB**: The heparin activity must be at a sufficient level to ensure lasting thromboresistance.	PASS
Side Branch Flow	This test evaluates the mean perfusion rates (mL/min) of fluid through the SB in a simulated use environment.	**SB**: The flow rate through the SB shall be characterized before, during, and after system deployment during simulated use testing.	Characterization
Pressure Drop	This test evaluates the pressure drop across the SB in a simulated use environment.	**SB**: In-vitro testing must demonstrate that the mean pressure drop shall be < 15 mmHg.	PASS
Sleeve Overhang	This test evaluates the amount of sleeve overhang at the proximal and distal ends of the device post-deployment.	**AC/SB**: The deployment sleeve overhang (length of the sleeve beyond the strut) for the Aortic and SB components shall be ≤ to 5 mm at each end of the stent-graft. In addition, the AC sleeve must not prohibit delivery and deployment of the SB component.	PASS
Transmural Leakage	This test determines the porosity of the graft material for an endovascular prosthesis constructed of non-textile materials.	**AC/AE:** The device must demonstrate no visible leakage of serous fluid when pressurized to 200 mmHg.	PASS
Water Permeability	This test evaluates the ability to resist water leakage through holes in the graft material under pressure.	**AC/AE/SB:** Characterize the water permeability of the devices. Refer to sealing for appropriate acceptance criteria.	Characterization
Device Luminal Surface	This test evaluates the structure of the inside lumen of the final deployed device.	**AC/AE/SB:** The average fibril length of the graft must meet specification.	PASS

Test	Test Purpose	Acceptance Criteria	Results
Delivery System			
Catheter Shaft to Hub Bond Strength*	Evaluate the bond strength of the catheter shaft to the deployment hub.	**AC/AE/SB**: The catheter shaft to hub assembly must have tensile bond strengths ≥ 7.0 lbs.	PASS
Olive and Transition Attachment Strength *	Evaluate the bond strength of the catheter leading olive and transition attachment.	**AC/AE/SB**: The bond strength of the olive-to-distal catheter shaft, transition-to-distal catheter shaft, and transition-to- catheter shaft shall be ≥ 7.0 lbs.	PASS
Deployment System Tensile Strength*	This test evaluates the strength of the bond between the deployment line and the deployment knob.	**AC/AE:** The tensile strength of the catheter deployment system must be > 7.0 lbs. **SB**: The tensile strength of the catheter deployment system must be > 5.0 lbs.	PASS
Catheter Leak	This test evaluates the leak resistance of the catheter.	**AC/AE/SB:** Pressure at which leakage of the delivery catheter guidewire lumen occurs shall be ≥ 300 kPa for all devices.	PASS
Catheter Torque	This test evaluates the torque strength of the catheter.	**AC/AE/SB:** The torque required to break the hub assembly to catheter bond shall be ≥ 13 in-oz.	PASS
Catheter Rotation	This test evaluates the ability of the catheter to rotate 360° without mechanical damage or failure.	**AC/AE:** The hub of the AC and AE catheter must rotate 360° without mechanical damage or failure when the leading end is fixed.	PASS
Retraction Force	This test evaluates the ability to safely withdraw the delivery system.	**AC/AE/SB:** The force to retract the catheter through the introducer sheath post-deployment must be < 7.0 lbs. for all sizes.	PASS
Guidewire Compatibility*	This test evaluates the device compatibility with the specified guidewire.	**AC/AE/SB:** The catheter and removable guidewire tube must be compatible with a 0.035” or smaller guidewire. The guidewire shall pass freely through the catheter without obstruction.	PASS
Flushable Guidewire Lumen*	This test evaluates the flushability of the guidewire lumen.	**AC/AE/SB:** The guidewire lumen of the catheter must be flushable with water or saline whereby fluid enters at the guidewire/flush port and exist at the leading end of the catheter through the guidewire lumen.	PASS
*Testing was also completed to support the 36-month shelf-life study (See Section IX-D).			
** GORE® TAG® Conformable Thoracic Endoprosthesis device testing leveraged due to similarities in processing and design.			

B. Animal Studies

The GORE® TAG® Thoracic Branch Endoprosthesis was subjected to 2 (two) GLP animal studies to evaluate the safety and performance of the device. The GLP *in vivo* animal study demonstrated the safety and overall product performance of the GORE® TAG® Thoracic Branch Endoprosthesis *in vivo* in a total of 13 domestic swine. **Table 3** summarizes the result of the GLP study conducted on finished, sterile devices.

Table 3: Summary Result of the GLP Animal Study

Study Description	Study Overview	Purpose	Summary of Test Results
#2156SC An acute evaluation of the GORE® TAG® Thoracic Branched Endoprosthesis in the swine model	- Animal Model: 3 Domestic swine - Anatomical Deployment Location: Thoracic aorta/left subclavian artery - Responses Evaluated: Assessed delivery system performance and functional performance (at 0 days) assessed against acceptance criteria	To evaluate the delivery system performance and functional performance of the GORE® TAG® Thoracic Branch Endoprosthesis (AC, SB, AE) and accessory devices.	Delivery performance: Passing scores for all delivery performance attributes. Functional performance: Passing scores for all functional performance attributes. No abnormal necropsy findings were observed.
#2155SC* GORE® TAG® Thoracic Branched Endoprosthesis evaluation in the porcine left subclavian artery	- Animal Model: Domestic swine (10 at day 0, 6 at 90 days and 3 at 180 days) - Anatomical Deployment Location: Thoracic aorta/left subclavian artery - Responses Evaluated: Delivery system performance (n=10) and functional performance (n=6 at 90 days, n=3 at 180 days)	To evaluate the delivery system and the long-term functional performance of the GORE® TAG® Thoracic Branch Endoprosthesis (AC/SB) in the left subclavian artery position.	Delivery performance: Passing scores for all attributes. Functional performance: Passing scores for all attributes. No abnormal necropsy findings were observed.

*#2155 was also used to assess the biocompatibility endpoint for *in vivo* thrombogenicity for the SB and AC.

C. Biocompatibility Studies

Biocompatibility testing was conducted on the GORE® TAG® Thoracic Branch Endoprosthesis in accordance with applicable Good Laboratory Practices (21 CFR §58) and ISO 10993-1: 2009, Biological Evaluation of Medical Devices.

The GORE® TAG® Thoracic Branch Endoprosthesis delivery systems are classified as externally communicating in limited contact (< 24 hrs) with circulating blood. The stent-grafts are classified as an implant device in permanent contact (> 30 days) with circulating blood.

All testing performed met the pre-specified acceptance criteria. A summary of the biocompatibility testing conducted can be found in **Table 4**.

Table 4: Summary of GORE® TAG® Thoracic Branch Endoprosthesis Implant Biocompatibility Testing

Test Performed	Test Purpose	Acceptance Criteria	Results
Cytotoxicity	To determine if device extracts cause cytotoxicity	Test article extract cytotoxicity score is ≤ 2.	**PASS**
Sensitization	To evaluate the allergenic potential or sensitizing capacity of device extracts	Test article extracts do not elicit a dermal observation grade > 1 at the challenge provided the control group did not also receive grades > 1.	**PASS**
Irritation / Intracutaneous Reactivity	To determine if any chemicals that may leach or be extracted from the test article were capable of causing local irritation	The difference in the average scores between test and control extracts is ≤ 1.	**PASS**
Acute Systemic Toxicity	To screen device extracts for potential toxic effects as a result of single-dose systemic injections	None of the animals treated with test extracts exhibit significantly greater biological reactions than control animals.	**PASS**
Pyrogenicity	To determine if a saline extract of the device causes a febrile response	Temperature increases in individual animals treated with test article extract are each ≤ 0.5°C.	**PASS**

Test Performed	Test Purpose	Acceptance Criteria	Results
Implantation	Evaluate the local effects of a device in direct contact with living skeletal muscle tissue	Histological evaluation of implant sites, aided by gross observation at necropsy, indicate that tissue responses surrounding test article implants are not significantly greater than those associated with the negative control article.	**PASS**
Hemocompatibility Hemolysis	To evaluate the hemolytic potential of the device	Hemolytic indices above the negative controls for the direct contact and extraction evaluations are both ≤ 2%.	**PASS**
Hemocompatibility Complement	To measure complement activation when serum is exposed to a device which indicates whether a device is capable of generating activation fragment SC5b-9, which contributes to the inflammatory immune response	The test article is not considered to have a clinically relevant effect on SC5b-9 complement activation.	**PASS***
Hemocompatibility Thrombogenicity	To evaluate the potential of the test device to resist thrombus formation when placed in the vasculature as evaluated in an animal study.	SB and AC: Characterization only AE: Thrombus and patency scores for the test article are not substantially worse than those for the commercial, control article (≤ 2 point difference).	**PASS**
Genotoxicity Carcinogenicity Reproductive and Developmental Toxicity Subchronic/ Chronic Toxicity	To determine whether long-term (>30 days) patient exposure to levels of exhaustively extracted chemicals from the test articles could produce unacceptable human health risks, including carcinogenic and systemic non-carcinogenic risks.	Refer to Chemical characterization and Toxicological Risk Assessment	**PASS**

* The AC and AE components did not activate SC5b-9 fragments *in vitro*. The SB implant generated statistically significant levels of SC5b-9 fragments in the *in vitro* complement activation assay compared to a negative reference material. All final SC5b-9 concentrations recorded in the complement activation assay of the SB component, including those for all control articles except for Normal Human Serum at rest, are on the high end of historical ranges of this study and, thus, strongly suggest non-specific signal elevation in this particular assay.

Neither a 180-day preclinical porcine study nor a human clinical trial spanning 8 years have revealed any evidence of complement activation. Furthermore, all of the materials comprising the SB implant are used in commercial GORE medical devices with successful clinical histories. Therefore, the results for SB complement activation were determined to be acceptable.

Table 5: Summary of GORE® TAG® Thoracic Branch Endoprosthesis Delivery System Biocompatibility Testing

Test Performed	Test Purpose	Acceptance Criteria	Results
Cytotoxicity	To determine if device extracts cause cytotoxicity	Test article extract cytotoxicity score is ≤ 2.	**PASS**
Sensitization	To evaluate the allergenic potential or sensitizing capacity of delivery system extracts	Test article extracts do not elicit a dermal observation grade > 1 at the challenge provided the control group did not also receive grades > 1.	**PASS**
Irritation / Intracutaneous Reactivity	To determine if any chemicals that may leach or be extracted from the test article were capable of causing local irritation	The difference in the average scores between test and control extracts is ≤ 1.	**PASS**
Acute Systemic Toxicity	To screen delivery system extracts for potential toxic effects as a result of single-dose systemic injections	None of the animals treated with test extracts exhibit significantly greater biological reactions than control animals.	**PASS**
Pyrogenicity	To determine if a saline extract of the delivery system causes a febrile response	Temperature increases in individual animals treated with test article extract are each ≤ 0.5°C.	**PASS**
Hemocompatibility Hemolysis	To evaluate the hemolytic potential of the delivery system	Hemolytic indices above the negative controls for the direct contact and extraction evaluations are both ≤ 2%.	**PASS**
Hemocompatibility Complement	To measure complement activation when serum is exposed to a delivery system which indicates whether a delivery system is capable of generating activation fragment SC5b-9, which contributes to the inflammatory immune response	The test article is considered to have no effect on complement activation if the SC5b-9 concentration is not statistically different than the negative reference material or if the test article results are statistically significantly less than the negative reference material.	**PASS**

Test Performed	Test Purpose	Acceptance Criteria	Results
Hemocompatibility Thrombogenicity	To evaluate the potential of the test delivery system to resist thrombus formation when placed in the vasculature as evaluated in an animal study.	All animals survived the general anesthesia and study observation interval, and the patency and thrombus scores were not subjectively different between the test and control articles.	**PASS**

D. Sterilization, Packaging, and Shelf-Life

The GORE® TAG® Thoracic Branch Endoprosthesis is sterilized by Ethylene Oxide (EO). Validation of the sterilization method to ensure a Sterility Assurance Level (SAL) of 10^{-6} has been conducted in accordance with ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

Packaging Validation demonstrated the ability of the packaging to protect the product and maintain a sterile barrier through shipping and shelf life.

A shelf life of three (3) years has been established for the GORE® TAG® Thoracic Branch Endoprosthesis based on product and package shelf-life testing. The specific engineering tests completed to support the shelf-life are denoted by an asterisk (*) in **Table 2**.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study (SSB 11-02) to establish a reasonable assurance of safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery in the US under IDE # G130120. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between September 2016 and October 2019. The database for this PMA reflected data collected through April 12, 2021 and included 238 patients. There were 40 investigational sites in the US.

The study was a prospective, multicenter, non-randomized clinical study with two (2) study arms specific to proximal placement of the device in Zone 2 with a total of four (4) cohorts. The arms are described as follows:

- Zone 2 – Aneurysm Arm/Cohort: Primary enrollment cohort with hypothesis-driven analysis

- Zone 2 – Non-aneurysm Arm: Descriptive analysis
    - Dissection Cohort
    - Traumatic Transection Cohort
    - Other isolated lesion types (Other Isolated Lesions are Non-Aneurysm, Non-Traumatic Transection, or Non- Dissection lesions with non-diseased proximal and distal landing zones for example intramural hematomas, aortic ulcers etc.)

Each cohort was analyzed separately by lesion type.

The primary endpoint was a composite of the following events from the time of enrollment through 12 months:

- Device Technical Success
- Absence of the following:
    - Aortic rupture;
    - Lesion-related mortality;
    - Disabling stroke (within 30 days);
    - Permanent paraplegia (within 30 days);
    - Permanent paraparesis (within 30 days);
    - New onset renal failure requiring permanent dialysis (within 30 days);
    - Additional unanticipated post-procedural surgical or interventional procedure related to the device, procedure, or withdrawal of the delivery system.

Primary endpoint (mixture of safety and effectiveness) success was defined as the proportion of analysis-eligible subjects without a primary endpoint event that met all of the endpoint components (described above) and with 12-Month imaging performed. The Aneurysm Cohort was the only cohort with a performance goal to be tested. The results were tested against a performance goal of 64%, derived from historical GORE TAG® Thoracic Endoprosthesis and Conformable GORE® TAG® Thoracic Endoprosthesis study data (P040043). The hypothesis tested against a one-sided alpha level of 0.05 was:

Null hypothesis (H_O): $p \leq 0.64$

Alternative hypothesis (H_A): $p > 0.64$

Where p is the proportion of Subjects with primary endpoint success, as described above.

No hypothesis tests were planned for the Non-Aneurysm Cohorts.

GORE® TAG® Thoracic Branch Endoprosthesis Aneurysm feasibility data (G130120) was used to estimate primary endpoint success to be 78% in Aneurysm. Using the Exact Binomial Test and assuming a one-sided alpha of 0.05, a performance goal of 64%, and power of at least 80%, the sample size needed was 70 patients. Assuming 18% attrition, the sample size required was 85 patients.

Evaluation groups used during the course of the pivotal study are described below:

- During the screening process, all patients who were assessed by an Investigator to meet all inclusion / exclusion criteria were submitted to Gore for review and case approval. At the conclusion of the process, the site was notified by Gore on the patient's eligibility (Accept / Reject).
- An independent external Core Laboratory (Core Lab) was used to perform evaluations on all medical imagery submitted by clinical sites. The Core Lab reported all measurements and device assessments to Gore.
- An external Clinical Events Committee (CEC) adjudicated safety and certain effectiveness endpoint events for the study as well as reviewed inclusion / exclusion violations for potential impact on subject safety. Effectiveness endpoint events not adjudicated by the CEC were determined by the Core Lab.
- An independent Data Safety Monitoring Board (DSMB) reviewed all available safety data on a regular basis and provided recommendations on the continuing safety, validity and scientific merit of the study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the SSB 11-02 study arms described above was limited to patients who met the following inclusion criteria:

- Presence of thoracic aortic pathology deemed to warrant surgical repair which requires proximal graft placement in Zone 2.
- Age ≥18 years at time of informed consent signature
- Subject is capable of complying with protocol requirements, including follow-up.
- Informed Consent Form (ICF) is signed by Subject or legal representative
- Must have appropriate proximal aortic landing zone.
- Must have appropriate target branch vessel landing zone.
- For patients with aneurysm/isolated lesion, must have appropriate distal aortic landing zone.

Patients were not permitted to enroll in the SSB11-02 study arms described above if they met any of the following exclusion criteria:

- Concomitant disease of the ascending aorta or aneurysm of the abdominal aorta requiring repair
- Previous endovascular repair of the ascending aorta
- Previous endovascular repair of the DTA with a non-Gore device
- Surgery within 30 days prior to enrollment, with the exception of surgery for Ascending Aortic Dissection and/or placement of vascular conduit for access, or surgery to treat any other presenting injuries in Traumatic Transection Subjects only.

- Infected aorta
- Life expectancy <2 years
- Myocardial infarction within 6 weeks prior to treatment
- Stroke within 6 weeks prior to treatment, stroke defined as rapidly developing clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin.
- Patient has a systemic infection and may be at increased risk of endovascular graft infection
- Pregnant female at time of informed consent signature
- Degenerative connective tissue disease, e.g. Marfan's or Ehler-Danlos Syndrome
- Participation in another drug or medical device study within one year of study enrollment
- Known history of drug abuse within one year of treatment
- Presence of protruding and/or irregular thrombus and/or atheroma in the aortic arch or ascending aorta
- Tortuous or stenotic iliac and/or femoral arteries preventing introducer sheath insertion and the inability to use a conduit for vascular access
- Planned coverage of celiac artery
- Patient has known sensitivities or allergies to the device materials
- Patient has known hypersensitivity or contraindication to anticoagulants or contrast media, which is not amenable to pre-treatment
- Previous instance of Heparin Induced Thrombocytopenia Type 2 (HIT-2) or known hypersensitivity to heparin
- Patient with a history of a hypercoagulability disorder and/or hypercoagulability state
- Diameter taper outside of the device sizing range between proximal and distal landing zones of aorta and the inability to use additional devices of different diameters to compensate for the taper
- Mycotic aneurysm
- Persistent refractory shock (systolic blood pressure <90 mm Hg)
- Patient has body habitus or other medical condition which prevents adequate visualization of the aorta
- Renal failure defined as patients with an estimated Glomerular Filtration Rate (eGFR) <30 or currently requiring dialysis

2. Follow-up Schedule

All patients were required to return for follow-up examinations at 1, 6, 12, 24, 36, 48 and 60 months. **Table 6** outlines the required screening evaluations and follow-up visit procedures for subjects.

Table 6: Schedule of Events

	Pre-Treatment	Treatment	Discharge	1 month	6 months	Annually for up to 5 years
Physical examination	X		X	X	X	X
Serum Creatinine Concentration	X					
Spiral CTA (contrast)	X			X	X	X
Spiral CT (non-contrast)				X		
Angiogram		X				

3. Clinical Endpoints

With regards to safety and effectiveness, the primary endpoint for all cohorts was a composite of the following events through 12 months:

- Device Technical Success
  - *Successful access and delivery to the intended implantation site, and retrieval of the device delivery system, and;*
  - *Patency of the graft, and;*
  - *The absence of unanticipated additional procedure related to the device, procedure, or withdrawal of the delivery system*
- Absence of the following:
  - Aortic rupture
  - Lesion-related mortality
  - Disabling stroke
    - *Stroke was assessed using the Modified Rankin Scale (mRS). Stroke identified as having occurred within 30 days of the index endovascular procedure, combined with mRS≥2 with an increase from baseline of at least one grade due to neurological deficits at no more than 120 days post index endovascular procedure.*
  - Permanent paraplegia
    - *Paraplegia secondary to Spinal Cord Ischemia (SCI) identified within 30 days of the index endovascular procedure combined with SCI scale grade = 3 at the one month follow-up visit.*
  - Permanent paraparesis
    - *Paraparesis secondary to SCI identified within 30 days of the index endovascular procedure, combined with SCI scale grade = 2 at the one month follow-up visit.*

- New onset renal failure requiring permanent dialysis
  - *New onset sustained renal failure identified within 30 days of the index endovascular procedure, combined with need/requirement for dialysis at the one month follow-up visit.*
- Additional unanticipated post-procedural surgical or interventional procedure related to the device, procedure, or withdrawal of the delivery system

With regard to overall study success, the primary endpoint performance goal of 64% for the Aneurysm cohort needed to be met in order to achieve study success. The primary endpoint analysis for the other cohorts (Dissection, Traumatic Transection and Other Isolated Lesion) was analyzed for each cohort and was reported descriptively (no hypothesis tests).

In addition to the primary endpoint analysis, Procedural and Treatment Success data was collected and analyzed for each cohort and were reported descriptively and independent of the performance goal.

- Procedural Success- defined as Device Technical Success, with absence of the following from the initiation of the endovascular procedure through the one month follow-up window (59 days) unless otherwise noted below:
  - Death (Through 30 days only)
  - Aortic rupture (Through 30 days only)
  - Disabling stroke (Through 30 days only)
  - Paraplegia (Through 30 days only)
  - Paraparesis (Through 30 days only)
  - New onset renal failure requiring dialysis (Through 30 days only)
  - Additional unanticipated surgical (including conversion to open surgery) or interventional (placement of additional unanticipated endovascular devices) procedure related to the device, procedure, or withdrawal of the delivery system
  - New ischemia
  - Distal device-related thromboembolic adverse event requiring intervention or surgery
  - Extension of a dissection (proximally or distally) (Dissection cohort only)
  - New dissection
  - Life-threatening bleed (Through 30 days only)
  - Myocardial infarction (Through 30 days only)
  - Prolonged intubation
  - Laryngeal or Phrenic Nerve injury (Through 30 days only)
  - Renal dysfunction or volume overload requiring ultrafiltration
  - Severe Heart Failure/Hypotension

- Treatment Success- defined as Device Technical Success with absence of the following events occurring from the initiation of the index endovascular procedure and at all appropriate follow-up windows:
    - Aortic enlargement in the region encompassed by the initial lesion
    - Aortic rupture
    - Extension of a dissection (proximally or distally) (Dissection cohort only)
    - New dissection
    - False lumen perfusion through the primary entry tear (Dissection cohort only)
    - False lumen perfusion through an aortic arch branch vessel (Dissection cohort only)
    - Type I or III endoleak
    - Fistula formation
    - Lesion-related mortality
    - Loss of device integrity
    - Loss of aortic or aortic branch patency
    - Migration
    - Disabling stroke within 30 days of the index endovascular procedure only
    - Paraplegia within 30 days of the index endovascular procedure only
    - Paraparesis within 30 days of the index endovascular procedure only
    - New ischemia
    - Additional unanticipated surgical (including conversion to open surgery) or interventional (placement of additional unanticipated endovascular devices) procedure related to the device, procedure, or withdrawal of the delivery system

The following outcomes, which were not components of Procedural or Treatment Success, were pre-defined as additional outcomes within the study protocol and collected:

- Type II endoleak
- Type IV endoleak
- Significant Blood Loss
- False Lumen Status in treated and untreated segments (Dissection cohort only)
- False Lumen perfusion through a non-aortic arch branch vessel (Dissection cohort only)

B. Accountability of PMA Cohort

At the time of database lock, 238 patients were eligible and included for analysis. Two patients were excluded from analysis due to a major protocol deviation. **Table 7** and **Table 8** summarize compliance with the follow-up visit and imaging requirements directed by the investigational plan for enrolled Aneurysm and Dissection Subjects.

Table 7: Subject Disposition and Compliance by Study Period for Aneurysm Cohort

		Subjects with Data for Visit					Adequate Imaging to Assess Parameter[2]					Subject Status			
Visit	**Eligible for Follow-Up**	**Subjects with Data for that Visit**	**Physical Exam**	**CT**	**MRA**	**Subjects with Follow-Up Pending[1]**	**Size Increase (Aortic Enlargement)**	**Endoleak**	**Device Migration**	**Wire Fracture**	**Device Patency**	**Death**	**Conversion**	**LTF[3]**	**Not Due for Next Visit[4]**
Endovascular Procedure	84	84 (100.0%)	-	-	-	0 (0%)	-	-	-	-	84 (100.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	84	82 (97.6%)	80 (95.2%)	13 (15.5%)	0 (0%)	0 (0%)	-	12 (14.3%)	13 (15.5%)	13 (15.5%)	13 (15.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 Month	84	79 (94.0%)	78 (92.9%)	72 (85.7%)	1 (1.2%)	0 (0%)	-	69 (82.1%)	72 (85.7%)	72 (85.7%)	70 (83.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 Months	84	76 (90.5%)	72 (85.7%)	74 (88.1%)	0 (0%)	0 (0%)	62 (73.8%)	72 (85.7%)	73 (86.9%)	73 (86.9%)	72 (85.7%)	3 (3.6%)	0 (0%)	1 (1.2%)	0 (0%)
12 Months	80	74 (92.5%)	69 (86.3%)	68 (85.0%)	1 (1.3%)	0 (0%)	57 (71.3%)	66 (82.5%)	67 (83.8%)	66 (82.5%)	67 (83.8%)	2 (2.5%)	0 (0%)	2 (2.5%)	0 (0%)
24 Months	76	64 (84.2%)	55 (72.4%)	53 (69.7%)	0 (0%)	0 (0%)	47 (61.8%)	51 (67.1%)	53 (69.7%)	53 (69.7%)	51 (67.1%)	5 (6.6%)	0 (0%)	3 (3.9%)	0 (0%)
36 Months	68	37 (54.4%)	29 (42.6%)	33 (48.5%)	0 (0%)	24 (35.3%)	25 (36.8%)	26 (38.2%)	28 (41.2%)	28 (41.2%)	27 (39.7%)	1 (1.5%)	0 (0%)	2 (2.9%)	33 (48.5%)
48 Months	32	4 (12.5%)	2 (6.3%)	4 (12.5%)	0 (0%)	28 (87.5%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	0 (0%)	0 (0%)	0 (0%)	32 (100.0%)

[1]Subjects still within follow-up window, but data not yet available.
[2]Not the number of Subjects with these reported events, but rather, the number with adequate imaging as assessed by Core Lab, such as paired size data to evaluate aneurysm growth. Wire fracture is if at least partially evaluable.
[3]In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including Subjects that have withdrawn from the study.
[4]Those Subjects that are "Not due for next visit" are those subjects that are not within the follow-up window for the next interval.
Study period definitions: Endovascular Procedure (0 days) Post-Procedure (1-14 days) 1 Month (15-59 days) 6 Months (60-242 days) 12 Months (243-546 days) 24 Months (547-911 days) 36 Months (912-1275 days) 48 Months (1276-1640 days) 60 Months (1641-2006 days)

Table 8: Subject Disposition and Compliance by Study Period for Dissection Cohort

		Subjects with Data for Visit					Adequate Imaging to Assess Parameter[2]					Subject Status			
Visit	**Eligible for Follow-Up**	**Subjects with Data for that Visit**	**Physical Exam**	**CT**	**MRA**	**Subjects with Follow-Up Pending[1]**	**Size Increase (Aortic Enlarge-ment)**	**Endoleak**	**Device Migration**	**Wire Fracture**	**Device Patency**	**Death**	**Conversion**	**LTF[3]**	**Not Due for Next Visit[4]**
Endovascular Procedure	132	132 (100.0%)	-	-	-	0 (0%)	-	-	-	-	132 (100.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	132	129 (97.7%)	124 (93.9%)	17 (12.9%)	0 (0%)	0 (0%)	-	17 (12.9%)	16 (12.1%)	17 (12.9%)	16 (12.1%)	4 (3.0%)	0 (0%)	0 (0%)	0 (0%)
1 Month	128	119 (93.0%)	118 (92.2%)	109 (85.2%)	0 (0%)	0 (0%)	-	106 (82.8%)	109 (85.2%)	104 (81.3%)	107 (83.6%)	2 (1.6%)	0 (0%)	0 (0%)	0 (0%)
6 Months	126	113 (89.7%)	97 (77.0%)	108 (85.7%)	1 (0.8%)	0 (0%)	95 (75.4%)	103 (81.7%)	107 (84.9%)	102 (81.0%)	106 (84.1%)	5 (4.0%)	0 (0%)	0 (0%)	0 (0%)

		Subjects with Data for Visit					Adequate Imaging to Assess Parameter[2]					Subject Status			
Visit	Eligible for Follow-Up	Subjects with Data for that Visit	Physical Exam	CT	MRA	Subjects with Follow-Up Pending[1]	Size Increase (Aortic Enlarge-ment)	Endoleak	Device Migration	Wire Fracture	Device Patency	Death	Conversion	LTF[3]	Not Due for Next Visit[4]
12 Months	121	103 (85.1%)	99 (81.8%)	98 (81.0%)	0 (0%)	1 (0.8%)	90 (74.4%)	94 (77.7%)	97 (80.2%)	94 (77.7%)	95 (78.5%)	3 (2.5%)	0 (0%)	3 (2.5%)	2 (1.7%)
24 Months	113	76 (67.3%)	64 (56.6%)	68 (60.2%)	0 (0%)	24 (21.2%)	59 (52.2%)	60 (53.1%)	64 (56.6%)	60 (53.1%)	61 (54.0%)	4 (3.5%)	0 (0%)	2 (1.8%)	32 (28.3%)
36 Months	75	35 (46.7%)	29 (38.7%)	32 (42.7%)	0 (0%)	30 (40.0%)	29 (38.7%)	25 (33.3%)	29 (38.7%)	28 (37.3%)	25 (33.3%)	0 (0%)	0 (0%)	1 (1.3%)	38 (50.7%)
48 Months	36	6 (16.7%)	5 (13.9%)	6 (16.7%)	0 (0%)	28 (77.8%)	3 (8.3%)	4 (11.1%)	4 (11.1%)	4 (11.1%)	4 (11.1%)	1 (2.8%)	0 (0%)	2 (5.6%)	33 (91.7%)

[1]Subjects still within follow-up window, but data not yet available.
[2]Not the number of Subjects with these reported events, but rather, the number with adequate imaging as assessed by Core Lab, such as paired size data to evaluate aneurysm growth. Wire fracture is if at least partially ev
[3]In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including subjects that have withdrawn from the study.
[4]Those Subjects that are "Not due for next visit" are those Subjects that are not within the follow-up window for the next interval.
Study period definitions: Endovascular Procedure (0 days) Post-Procedure (1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

Subject compliance with follow-up visits and imaging requirements for the Traumatic Transection and Other Isolated Lesion Cohorts is summarized below:

- Traumatic Transection Cohort: All nine (100%) eligible Subjects in this cohort had a 1-Month visit and imaging. Seven (77.8%) Subjects had their 12-Month visit (66.7% had imaging). All nine Subjects were through the 12-Month follow-up window, with four Subjects in the 24-Month window and five in the 36-Month window. There have been no deaths or discontinuations in this cohort.
- Other Isolated Lesion Cohort: Twelve (92.3%) of the 13 Subjects in this cohort had a 1-Month visit and imaging. Eleven Subjects were eligible for a 12-Month follow-up visit, and 9 (81.8%) Subjects had their 12-Month visit (72.7% had imaging). Two Subjects were still in the 12-Month window, with four in the 24-Month window, one in the 36-Month window, and one in the 48-Month window. There have been four deaths and one non-death discontinuation in this cohort.

C. Study Population Demographics and Baseline Parameters

1. Demographics

The demographics of the study population are typical for a thoracic endovascular graft study performed in the US.

A summary of Subject demographics can be found in **Table 9**. The majority of Subjects were male (63.1% for Aneurysm, 75.0% for Dissection, 88.9% for Traumatic Transection, and 46.2% for Other Isolated Lesion). Most Subjects also specified white as their race (79.8% for Aneurysm, 72.7% for Dissection, 55.6% for Traumatic Transection, and 69.2% for Other Isolated Lesion). The median ages reported were 72 years for Aneurysm, 64 years for Dissection, 43 years for Traumatic Transection, and 67 years for Other Isolated Lesion.

Table 9: Baseline Demographics

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Sex					
Male	53 (63.1%)	99 (75.0%)	8 (88.9%)	6 (46.2%)	166 (69.7%)
Female	31 (36.9%)	33 (25.0%)	1 (11.1%)	7 (53.8%)	72 (30.3%)
Ethnicity					
Not Hispanic or Latino	82 (97.6%)	123 (93.2%)	5 (55.6%)	10 (76.9%)	220 (92.4%)
Hispanic or Latino	2 (2.4%)	7 (5.3%)	4 (44.4%)	3 (23.1%)	16 (6.7%)
Unknown	0 (0%)	2 (1.5%)	0 (0%)	0 (0%)	2 (0.8%)

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Race[1]					
White	67 (79.8%)	96 (72.7%)	5 (55.6%)	9 (69.2%)	177 (74.4%)
Black or African American	12 (14.3%)	29 (22.0%)	0 (0%)	2 (15.4%)	43 (18.1%)
Asian	4 (4.8%)	3 (2.3%)	0 (0%)	0 (0%)	7 (2.9%)
American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hawaiian or Pacific Islander	2 (2.4%)	1 (0.8%)	0 (0%)	0 (0%)	3 (1.3%)
Other	0 (0%)	3 (2.3%)	4 (44.4%)	2 (15.4%)	9 (3.8%)
Age (yrs)					
N	84	132	9	13	238
Mean (Std Dev)	70.3 (11.11)	62.5 (11.29)	42.4 (18.95)	64.8 (13.28)	64.6 (12.93)
Median	72.0	64.0	43.0	67.0	67.0
Range	(33, 87)	(23, 88)	(22, 76)	(30, 79)	(22, 88)
BMI					
N	84	132	9	13	238
Mean (Std Dev)	28.8 (6.30)	30.5 (6.47)	29.5 (5.03)	25.8 (5.33)	29.6 (6.39)
Median	28.3	29.5	29.1	25.8	29.0
Range	(18.9, 51.7)	(16.0, 53.9)	(23.8, 38.8)	(18.9, 38.4)	(16.0, 53.9)

[1]One Zone 2 Aneurysm Subject had two races selected (Asian and Pacific Islander)

2. Subject Baseline Medical History

A summary of the Subject baseline medical history is provided in **Table 10**. The majority of Subjects had a medical history of hypertension (89.9%).

Table 11 summarizes Subject risk factors prior to enrollment. Most Subjects (70.2% for Aneurysm, 66.7% for Dissection, 44.4% for Traumatic Transection, and 69.3% for Other Isolated Lesion) had an American Society of Anesthesiologists (ASA) classification of III or higher. The majority of Subjects were classified as NYHA I or higher (62.6%), with only 37.4% of Subjects having no cardiac disease. The median Society of Vascular Surgeon's (SVS) risk score was 4.9 for the Aneurysm cohort, 5.3 for Dissection, 1.6 for Traumatic Transection, and 5.2 for Other Isolated Lesions. Approximately one third of the Subjects had a history of previous aortic surgery (38.1% for Aneurysm, 27.3% for Dissection, and 53.8% for Other Isolated Lesions), most commonly of the ascending aorta (56.0%).

Table 10: Baseline Medical History

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Atrial fibrillation	16/83 (19.3%)	25/132 (18.9%)	0/9 (0%)	4/13 (30.8%)	45/237 (19.0%)
Cancer	21/83 (25.3%)	20/130 (15.4%)	1/9 (11.1%)	1/13 (7.7%)	43/235 (18.3%)
Cardiac arrhythmia	15/83 (18.1%)	46/132 (34.8%)	0/9 (0%)	5/13 (38.5%)	66/237 (27.8%)
Chronic obstructive pulmonary disease	16/84 (19.0%)	16/131 (12.2%)	0/9 (0%)	3/13 (23.1%)	35/237 (14.8%)
Congestive heart failure	14/84 (16.7%)	11/132 (8.3%)	0/9 (0%)	0/13 (0%)	25/238 (10.5%)
Coronary artery bypass graft	12/83 (14.5%)	7/132 (5.3%)	0/9 (0%)	0/13 (0%)	19/237 (8.0%)
Coronary artery disease	27/83 (32.5%)	19/126 (15.1%)	1/9 (11.1%)	3/13 (23.1%)	50/231 (21.6%)
Diabetes mellitus	14/84 (16.7%)	19/132 (14.4%)	1/9 (11.1%)	2/13 (15.4%)	36/238 (15.1%)
Erectile dysfunction (males only)	7/27 (25.9%)	4/44 (9.1%)	1/5 (20.0%)	0/3 (0%)	12/79 (15.2%)
Great vessel stenosis	1/83 (1.2%)	1/129 (0.8%)	0/9 (0%)	0/11 (0%)	2/232 (0.9%)
Hypercholesterolemia	44/84 (52.4%)	55/127 (43.3%)	1/9 (11.1%)	6/13 (46.2%)	106/233 (45.5%)
Hypertension	72/84 (85.7%)	127/132 (96.2%)	4/9 (44.4%)	11/13 (84.6%)	214/238 (89.9%)
Myocardial infarction	14/83 (16.9%)	10/127 (7.9%)	0/9 (0%)	2/12 (16.7%)	26/231 (11.3%)
Nicotine use	30/84 (35.7%)	47/132 (35.6%)	2/9 (22.2%)	7/13 (53.8%)	86/238 (36.1%)
Other vascular intervention	11/83 (13.3%)	8/131 (6.1%)	0/9 (0%)	2/13 (15.4%)	21/236 (8.9%)
Paraplegia	1/84 (1.2%)	0/132 (0%)	0/9 (0%)	0/13 (0%)	1/238 (0.4%)
Percutaneous coronary intervention	14/82 (17.1%)	3/132 (2.3%)	0/9 (0%)	2/13 (15.4%)	19/236 (8.1%)
Peripheral vascular disease	11/83 (13.3%)	8/128 (6.3%)	1/9 (11.1%)	1/13 (7.7%)	21/233 (9.0%)
Prior aortic surgery	32/84 (38.1%)	36/132 (27.3%)	0/9 (0%)	7/13 (53.8%)	75/238 (31.5%)
Renal dialysis	0/83 (0%)	2/132 (1.5%)	1/9 (11.1%)	0/13 (0%)	3/237 (1.3%)
Renal insufficiency	14/84 (16.7%)	24/132 (18.2%)	1/9 (11.1%)	0/13 (0%)	39/238 (16.4%)
Stroke	12/84 (14.3%)	12/132 (9.1%)	1/9 (11.1%)	1/13 (7.7%)	26/238 (10.9%)
Subclavian steal	0/82 (0%)	0/126 (0%)	0/9 (0%)	0/9 (0%)	0/226 (0%)
Thromboembolic event	7/83 (8.4%)	10/132 (7.6%)	0/9 (0%)	0/13 (0%)	17/237 (7.2%)
Transient ischemic attack	6/84 (7.1%)	2/132 (1.5%)	0/9 (0%)	0/13 (0%)	8/238 (3.4%)
Valvular heart disease	20/83 (24.1%)	21/131 (16.0%)	0/9 (0%)	3/13 (23.1%)	44/236 (18.6%)

Table 11: Baseline Risk Factors

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Dominant left vertebral artery[1]	5/65 (7.7%)	5/105 (4.8%)	0/7 (0%)	1/6 (16.7%)	11/183 (6.0%)
Occluded/stenosed right vertebral artery[1]	1/69 (1.4%)	2/108 (1.9%)	0/7 (0%)	0/7 (0%)	3/191 (1.6%)
Aberrant right subclavian artery[1]	1/83 (1.2%)	4/128 (3.1%)	0/9 (0%)	3/12 (25.0%)	8/232 (3.4%)
Bilateral carotid artery disease[1]	5/73 (6.8%)	3/118 (2.5%)	0/8 (0%)	1/9 (11.1%)	9/208 (4.3%)
Presence of a left internal mammary artery graft[1]	5/82 (6.1%)	0/129 (0%)	0/9 (0%)	0/12 (0%)	5/232 (2.2%)
Incomplete circle of willis[1]	0/49 (0%)	0/78 (0%)	0/6 (0%)	0/6 (0%)	0/139 (0%)
Left vertebral artery ending in posterior inferior cerebellar artery[1]	0/47 (0%)	0/76 (0%)	0/5 (0%)	0/5 (0%)	0/133 (0%)
Clinical Frailty Scale Score (1-9, higher is more frail)					
n	83	131	8	13	235
Median	3.0	3.0	2.0	3.0	3.0
SVS Score (0-24, higher is worse)					
n	84	132	9	13	238
Median	5.0	5.0	0.0	4.0	5.0
ASA Classification					
I	5/84 (6.0%)	8/132 (6.1%)	2/9 (22.2%)	1/13 (7.7%)	16/238 (6.7%)
II	20/84 (23.8%)	36/132 (27.3%)	3/9 (33.3%)	3/13 (23.1%)	62/238 (26.1%)
III	39/84 (46.4%)	43/132 (32.6%)	0/9 (0%)	4/13 (30.8%)	86/238 (36.1%)
IV	20/84 (23.8%)	44/132 (33.3%)	4/9 (44.4%)	4/13 (30.8%)	72/238 (30.3%)
V	0/84 (0%)	1/132 (0.8%)	0/9 (0%)	1/13 (7.7%)	2/238 (0.8%)
NYHA Classification					
No cardiac disease	28/84 (33.3%)	48/132 (36.4%)	8/9 (88.9%)	5/13 (38.5%)	89/238 (37.4%)
I	31/84 (36.9%)	55/132 (41.7%)	1/9 (11.1%)	3/13 (23.1%)	90/238 (37.8%)
II	22/84 (26.2%)	24/132 (18.2%)	0/9 (0%)	5/13 (38.5%)	51/238 (21.4%)
III	3/84 (3.6%)	5/132 (3.8%)	0/9 (0%)	0/13 (0%)	8/238 (3.4%)
IV	0/84 (0%)	0/132 (0%)	0/9 (0%)	0/13 (0%)	0/238 (0%)

[1]Restricted to those with information known

3. Subject Baseline Treated Anatomy Information

A summary of the Subject baseline (Core Lab pre-imaging) aneurysm/lesion/treated segment diameters are provided in **Table 12**. Aneurysm Subjects had a median aneurysm diameter of 56.6 mm, Dissection Subjects had a median treated segment diameter of 47.2 mm, Traumatic Transection Subjects had a median lesion diameter of 34.8 mm, and Other Isolated Lesion Subjects had a median lesion diameter of 42.2 mm.

Table 12: Baseline Core Lab Aortic Treated (Aneurysm/Lesion/Treated Segment) Diameters

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Maximum Transverse Aortic Diameter of Aneurysm/Lesion[1] (mm)					
n	84	123	9	13	229
Median	56.6	47.2	34.8	42.2	50.2

[1]Maximum Aortic Diameter in Treated Segment for Dissection Subjects.

Table 13 summarizes the baseline (Core Lab) description of the extent of the Dissection treated in the Dissection cohort. For the majority of the Dissection Subjects, proximal extent of Dissection was Zone 2 (70.5%), although all of the Dissection Subjects required the device to be proximally landed in Zone 2. The distal extent of the treated dissection extended to the iliac arteries in the majority of Subjects (56.8%), followed by the abdominal aorta (12.9%), and then the DTA (12.1%, Zone 3-5).

Table 13: Baseline Core Lab Treated Dissection Extent for Zone 2 Dissection Cohort

	Zone 2 Dissection
Number of Enrolled Subjects	132
Proximal Extent of Dissection (Pre-Imaging, Core Lab)[1]	
Zone 0/1	0 (0%)
Zone 2	93 (70.5%)
Zone 3	26 (19.7%)
Zone 4	5 (3.8%)
Zone 5	0 (0%)
Distal Extent of Dissection (Pre-Imaging, Core Lab)[2]	
Aortic Arch (Zone 0,1,2)	0 (0%)
Descending Thoracic (Zone 3,4,5)	16 (12.1%)
Celiac (Zone 6)	4 (3.0%)
SMA (Zone 7)	3 (2.3%)
Renal(s) (Zone 8)	5 (3.8%)
Abdominal (Zone 9)	17 (12.9%)
Iliac(s) (Zone 10,11)	75 (56.8%)

[1]Eight subjects did not have this information reported and were not included in the table. Therefore, the total percentages do not equal 100%
[2] Twelve Subjects did not have this information reported and were not included in the table missing this information, therefore this does not add up to 100%.

4. Device Usage

Table 14 describes the initial treatment devices implanted in Subjects enrolled in the study. **Table 15** shows a summary of GORE® TAG® Thoracic Branch Endoprosthesis Aortic Component sizes implanted in the index procedure. **Table 16** and **Table 17** show a summary of the GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Sizing and Aortic Extender Sizing.

Table 14: Treatment Devices Implanted

	Aneurysm Arm		Non-Aneurysm Arm		Total
	Zone 2 Aneurysm	**Zone 2 Dissection**	**Zone 2 Traumatic Transection**	**Zone 2 Other Isolated Lesion**	**Zone 2**
Number of Enrolled Subjects	84	132	9	13	238
Number of Subjects with Both GORE® TAG® Thoracic Branch EndoprosthesesImplanted[1]	84 (100.0%)	131 (99.2%)	9 (100.0%)	13 (100.0%)	237 (99.6%)
Subjects with >1 Aortic Component Implanted	3 (3.6%)	1 (0.8%)	0 (0%)	0 (0%)	4 (1.7%)
Subjects with Aortic Extender Implanted	18 (21.4%)	13 (9.8%)	0 (0%)	1 (7.7%)	32 (13.4%)
Subjects with Other Devices Implanted[2]	2 (2.4%)	1 (0.8%)	0 (0%)	1 (7.7%)	4 (1.7%)
Subjects with CTAG as Distal Extension Implanted	43 (51.2%)	90 (68.2%)	0 (0%)	4 (30.8%)	137 (57.6%)
SB Components Implanted Per Subject[2]					
1 SB Component Implanted	76 (90.5%)	130 (98.5%)	9 (100.0%)	12 (92.3%)	227 (95.4%)
2 SB Components Implanted	8 (9.5%)	1 (0.8%)	0 (0%)	1 (7.7%)	10 (4.2%)
Aortic Extenders Implanted Per Subject					
0 Aortic Extenders	66 (78.6%)	119 (90.2%)	9 (100.0%)	12 (92.3%)	206 (86.6%)
1 Aortic Extender	15 (17.9%)	12 (9.1%)	0 (0%)	1 (7.7%)	28 (11.8%)
2 Aortic Extenders	3 (3.6%)	1 (0.8%)	0 (0%)	0 (0%)	4 (1.7%)

	Aneurysm Arm		Non-Aneurysm Arm		Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
CTAG Devices Implanted Per Subject					
0 CTAGs	41 (48.8%)	42 (31.8%)	9 (100.0%)	9 (69.2%)	101 (42.4%)
1 CTAG	30 (35.7%)	80 (60.6%)	0 (0%)	2 (15.4%)	112 (47.1%)
2 CTAGs	11 (13.1%)	9 (6.8%)	0 (0%)	2 (15.4%)	22 (9.2%)
3+ CTAGs	2 (2.4%)	1 (0.8%)	0 (0%)	0 (0%)	3 (1.3%)

[1]This includes both the aortic and side branch components.
[2]Other devices implanted included the following: One Subject used a GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis device to extend/reinforce the SB Component, another Subject had a GORE® VIABAHN® Endoprosthesis device plus a GORE® EXCLUDER® AAA Endoprosthesis device to treat an access related complication (iliac rupture), a third Subject had two GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis devices used as the SB Component (physician choice, due to difficulty advancing SB Component), and the last Subject had two GORE® VIABAHN® Endoprosthesis devices implanted to treat access related complications (iliac rupture).

Table 15: GORE® TAG® Thoracic Branch Endoprosthesis Aortic Component Sizing

Device Diameter (mm)	SB Portal Diameter (mm)	Device Length (cm)	Subjects (N=238)	Devices (N=242)
21	8	10	2 (0.8%)	2 (0.8%)
26	8	10	3 (1.3%)	3 (1.2%)
26	8	15	1 (0.4%)	1 (0.4%)
28	8	10	5 (2.1%)	5 (2.1%)
28	8	15	3 (1.3%)	3 (1.2%)
31	8	15	16 (6.7%)	16 (6.6%)
31	8	20	11 (4.6%)	11 (4.5%)
34	8	15	37 (15.5%)	37 (15.3%)
34	8	20	17 (7.1%)	17 (7.0%)
34	12	15	1 (0.4%)	1 (0.4%)
34	12	20	9 (3.8%)	9 (3.7%)
37	8	10	3 (1.3%)	3 (1.2%)
37	8	15	28 (11.8%)	28 (11.6%)
37	8	20	17 (7.1%)	17 (7.0%)
37	12	15	4 (1.7%)	4 (1.7%)
37	12	20	12 (5.0%)	12 (5.0%)
40	8	15	13 (5.5%)	13 (5.4%)
40	8	20	29 (12.2%)	31 (12.8%)
40	12	20	3 (1.3%)	3 (1.2%)
45	8	15	11 (4.6%)	11 (4.5%)
45	8	20	9 (3.8%)	9 (3.7%)
45	12	15	3 (1.3%)	3 (1.2%)
45	12	20	2 (0.8%)	3 (1.2%)

Table 16: GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Sizing

Device Diameter (mm)	SB Portal Diameter (mm)	Device Length (cm)	Subjects (N=237)	Devices (N=247)
8	8	6	3 (1.3%)	4 (1.6%)
10	8	6	22 (9.3%)	22 (8.9%)
12	8	6	100 (42.2%)	103 (41.7%)
15	8	6	66 (27.8%)	69 (27.9%)
15	12	6	25 (10.5%)	27 (10.9%)
17	8	6	13 (5.5%)	13 (5.3%)
17	12	6	8 (3.4%)	9 (3.6%)

Table 17: Initial Treatment GORE® TAG® Thoracic Branch Endoprosthesis Aortic Extender Sizing

Device Diameter (mm)	Device Length (cm)	Subjects (N=32)	Devices (N=36)
34	4.2	10 (31.3%)	12 (33.3%)
37	4.2	10 (31.3%)	11 (30.6%)
40	4.3	9 (28.1%)	10 (27.8%)
45	4.6	3 (9.4%)	3 (8.3%)

5. Procedure Characteristics

Table 18, **Table 19**, and **Table 20**summarize the endovascular procedure information by cohort. The majority of Subjects' (87.4%) proximal landing zone was within native aortic tissue, and 12.6% landed in a surgical graft (25 dissections subjects, four aneurysm subjects, and one was an other isolated lesion subject). The median procedure time was 132.5 minutes (154.5 minutes for the Aneurysm Cohort, 129 minutes for the Dissection Cohort, 109 minutes for the Traumatic Transection Cohort, and 142 minutes for the Other Isolated Lesion cohort). The access method for 69.7% of all Subjects was percutaneous, primarily through the right femoral artery (62.6%). Cut-down was used for 63 (26.5%) Subjects and cut-down with conduit in nine (3.8%) Subjects.

Table 18: Procedural Information – Part 1

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Proximal Landing Zone					
Within Surgical Graft	4 (4.8%)	25 (18.9%)	0 (0%)	1 (7.7%)	30 (12.6%)
Within Native Aorta	80 (95.2%)	107 (81.1%)	9 (100.0%)	12 (92.3%)	208 (87.4%)
Procedure Time[1] (minutes)					
n	84	132	9	13	238
Median	154.5	129.0	109.0	142.0	132.5

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Anesthesia Method					
General	83 (98.8%)	131 (99.2%)	9 (100.0%)	13 (100.0%)	236 (99.2%)
Regional	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	1 (0.4%)
Local	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	1 (0.4%)
Access Method					
Percutaneous	49 (58.3%)	105 (79.5%)	6 (66.7%)	6 (46.2%)	166 (69.7%)
Cut-down	28 (33.3%)	26 (19.7%)	3 (33.3%)	6 (46.2%)	63 (26.5%)
Cut-down and conduit	7 (8.3%)	1 (0.8%)	0 (0%)	1 (7.7%)	9 (3.8%)
Access Vessel					
Left femoral	21 (25.0%)	44 (33.3%)	5 (55.6%)	5 (38.5%)	75 (31.5%)
Right femoral	52 (61.9%)	85 (64.4%)	4 (44.4%)	8 (61.5%)	149 (62.6%)
Left iliac	3 (3.6%)	0 (0%)	0 (0%)	0 (0%)	3 (1.3%)
Right iliac	8 (9.5%)	3 (2.3%)	0 (0%)	0 (0%)	11 (4.6%)
Aortic	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Additional Access Sites[3]					
Left brachial	51 (60.7%)	97 (73.5%)	6 (66.7%)	9 (69.2%)	163 (68.5%)
Left axial	4 (4.8%)	6 (4.5%)	0 (0%)	1 (7.7%)	11 (4.6%)
Other[2]	28 (33.3%)	28 (21.2%)	2 (22.2%)	3 (23.1%)	61 (25.6%)

[1]Procedure Time (min) was captured as the time the first incision was made through the time the access site was closed.
[2]Other access sites may include a combination of multiple access sites including radial access and/or a combination of multiple access sites
[3]Three Subjects did not report additional access sites used, therefore, the total doesn't add up to 100%.

Table 19 highlights estimated blood loss, heparin usage, and adjunctive techniques used to prevent paraplegia for the Subjects. Eight (3.4%) Subjects had Site-reported blood loss ≥1000mL during the GORE® TAG® Thoracic Branch Endoprosthesis procedure. In total, 22 (9.2%) Subjects required a transfusion with a median replaced blood volume of 450mL. Heparin was administered on all Subjects with median dose administered of 10,000 units per mL. Overall, 45.4% of Subjects did not require adjunctive techniques to prevent paraplegia to be used. However, among those who did, CSF drainage was by far the most commonly used technique. As for additional procedures performed during procedure (not shown in table), there were 37 (15.6%) Subjects that required this, among them, 19 Subjects had an access-related additional procedure, 11 Subjects had an additonal procedure (e.g. stent, embolization, or ballooning) related to the treated area (one of these also had an access procedure), and the rest were due to other reasons, mainly around stent placement for renal perfusion in Dissection Subjects.

Table 19: Procedural Information – Part 2

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Contrast Used During Procedure (mL)					
n	84	130	8	13	235
Mean (Std Dev)	139.0 (99.28)	126.8 (53.76)	74.4 (17.82)	96.1 (29.13)	127.7 (73.09)
Estimated Blood Loss During Procedure (mL)					
n	83	130	9	13	235
Mean (Std Dev)	247.4 (340.61)	198.6 (708.18)	112.2 (97.57)	191.2 (242.02)	212.1 (566.94)
Blood Loss ≥ 1000mL	5 (6.0%)	3 (2.3%)	0 (0%)	0 (0%)	8 (3.4%)
Transfusion Required	11 (13.1%)	11 (8.3%)	0 (0%)	0 (0%)	22 (9.2%)
Transfusion Required, blood volume replaced (mL)					
n	9[2]	11	0	0	20
Mean (Std Dev)	678.9 (444.25)	1467.5 (2510.76)	-	-	1112.6 (1887.58)
Heparin Administered	84 (100.0%)	132 (100.0%)	9 (100.0%)	13 (100.0%)	238 (100.0%)
Heparin Administered, dose (units per mL) [3]					
n	76	124	9	13	222
Mean (Std Dev)	10098.7 (5039.19)	10791.9 (5318.91)	7444.4 (3643.87)	12230.8 (7811.89)	10503.2 (5368.16)
Adjunctive Technique Used to Prevent Paraplegia					
No	42 (50.0%)	49 (37.1%)	8 (88.9%)	9 (69.2%)	108 (45.4%)
Yes, CSF drainage	35 (41.7%)	70 (53.0%)	1 (11.1%)	4 (30.8%)	110 (46.2%)
Yes, induced hypertension	0 (0%)	5 (3.8%)	0 (0%)	0 (0%)	5 (2.1%)
Yes, CSF drainage and induced hypertension	2 (2.4%)	2 (1.5%)	0 (0%)	0 (0%)	4 (1.7%)
Yes, other[1]	5 (6.0%)	6 (4.5%)	0 (0%)	0 (0%)	11 (4.6%)

[1]Other adjunctive techniques included induced hypotension, permissive hypertension, and SSEP.
[2]Two Subjects did not have the transfusion volume recorded.
[3]There were eight Aneurysm and eight Dissection Subjects where the heparin dosage was not recorded.

Table 20 below outlines the length of hospital stay, with the median time being four days. Most Subjects (88.7%) were discharged home, 8.8% were sent to a rehab facility/nursing home, and 1.3% died in hospital (all three of these Subjects were in the Dissection cohort). The median time to return to normal activities was three days (four

days for Aneurysm Subjects, three days for Dissection Subjects, six days for Traumatic Transection Subjects, and two days for Other Isolated Lesion Subjects).

Table 20: Procedural Information – Part 3

	Aneurysm Arm	Non-Aneurysm Arm			Total
	Zone 2 Aneurysm	Zone 2 Dissection	Zone 2 Traumatic Transection	Zone 2 Other Isolated Lesion	Zone 2
Number of Enrolled Subjects	84	132	9	13	238
Length of Stay (days)					
n	84	132	9	13	238
Mean (Std Dev)	5.9 (5.49)	7.2 (8.21)	16.6 (17.04)	5.4 (3.59)	7.0 (7.89)
Discharge Location					
Home	74 (88.1%)	119 (90.2%)	7 (77.8%)	11 (84.6%)	211 (88.7%)
Rehabilitation center/nursing facility	9 (10.7%)	9 (6.8%)	1 (11.1%)	2 (15.4%)	21 (8.8%)
Acute care facility	1 (1.2%)	1 (0.8%)	1 (11.1%)	0 (0%)	3 (1.3%)
N/A - Subject died in hospital	0 (0%)	3 (2.3%)	0 (0%)	0 (0%)	3 (1.3%)
Return to Normal Activities (days)[1]					
n	84	129	9	13	235
Mean (Std Dev)	5.0 (5.11)	4.3 (3.51)	11.3 (11.50)	2.3 (1.25)	4.7 (4.77)
[1]Earliest reported time was used to calculate return to normal					

D. Safety and Effectiveness Results

The primary safety and effectiveness endpoint was a composite of the following events through the 12-month follow-up window: device technical success and freedom from the following: aortic rupture, lesion-related mortality, disabling stroke, permanent paraplegia or paraparesis, new onset renal failure requiring permanent dialysis, and unanticipated additional procedure related to the device/procedure.

1. Aneurysm: Primary Endpoint Composite

The pre-specified performance goal (PG) for freedom from Primary Endpoint events in the Aneurysm arm of 64% was met (n=74 Subjects eligible for Primary Analysis). The overall, rate of freedom from a primary endpoint event was 83.8% with a 95% one-sided Exact lower confidence limit of 75.1%.

Although there were 85 Subjects enrolled in this hypothesis-driven arm, one Subject was excluded due to having a CEC-adjudicated major Inclusion/Exclusion deviation (known history of drug abuse within one year of treatment) and ten Subjects were excluded due to lack of 12-month imaging being performed and not having a primary endpoint event, as pre-specified in the statistical plan. Therefore,

the overall primary endpoint composite denominator was comprised of the 69 Subjects with imaging performed in the 12-Month window and an additional five Subjects with a primary endpoint event through the 12-Months who did not have 12-Month imaging performed, leading to the n=74 Subjects eligible for the overall composite primary endpoint analysis.

Table 21: Primary Endpoint Composite Success for Aneurysm Cohort

Primary Endpoint Analysis	Endpoint Denominator	Endpoint Event	Percent Free from Endpoint Event (95% Exact LCL)	Reject Null Hypothesis (LCL > 64% PG)
Endpoint Eligible[1]	74	12	83.8% (75.1%)	Yes

[1]Primary Endpoint composite (Through 12 Months) denominator is restricted to those with primary endpoint event or 12 Month imaging performed. There has been one Subject excluded from this analysis due to having a CEC-adjudicated major inclusion/exclusion criteria violation.
NOTE: 95% LCL represents one-sided 95% Lower Confidence Limit by exact method.

Table 22: Primary Endpoint Component Events for Zone 2 Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	Total (Through 12 Months)
Number of Enrolled Subjects[1]	84	84	84	84	80	84
Number of Subjects with Imaging in Follow-Up Window	-	13	73	74	69	84
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	16	73	74	69	84
Subjects with Primary Endpoint Event[2] Below[3,5]	9/84 (10.7%)	5/16 (31.3%)	0/73 (0%)	0/74 (0%)	1/69 (1.4%)	12/74 (16.2%)
Device Technical Success failure[4]	7/84 (8.3%)	-	-	-	-	7/84 (8.3%)
Access or Device Delivery failure	4/84 (4.8%)	-	-	-	-	-
Access failure	0/84 (0%)	-	-	-	-	-
Accurate deployment failure	3/84 (3.6%)	-	-	-	-	-
Device delivery system retrieval failure	1/84 (1.2%)	-	-	-	-	-
Patency failure	0/84 (0%)	-	-	-	-	-
Unanticipated additional procedure related to device/procedure	4/84 (4.8%)	-	-	-	-	-
Aortic rupture	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/84 (0%)
Lesion-related mortality	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/84 (0%)
Disabling stroke[4]	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	3/84 (3.6%)
Permanent paraplegia[4]	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	-	-	1/84 (1.2%)
Permanent paraparesis[4, 5]	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	3/84 (3.6%)
New onset renal failure requiring permanent dialysis[4]	0/84 (0%)	0/84 (0%)	0/84 (0%)	-	-	0/84 (0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/84 (0%)	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	1/80 (1.3%)	1/84 (1.2%)

[1]Subjects at risk at the start of each interval.
[2]Definitions for all Primary Endpoints are in Section X (A) (3).
[3]Primary Endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window. Primary Endpoint composite Total (Through 12 Months) denominator is further restricted to primary endpoint event in timeframe (i.e. anytime ≤ 546 days; exceptions indicated with a '-' per Protocol definitions) and/or imaging done in 12 Month window (243-546). Primary Endpoint Component Event Rates are based on all enrolled subjects.
[4]Device technical success failure events on day 0 only, others are events with onset through day 30.
[5]One Subject had been CEC-adjudicated as having both Permanent paraplegia and permanent paraparesis. The CEC adjudication data has since been updated to reflect only having permanent paraplegia. A second Subject also had adjudication updated and no longer meets the definition of permanent paraparesis. This would result in an overall permanent paraparesis rate of 1.2% (1/84) and a change in the Primary Endpoint composite Total rate to 15.1% (11/73; the second Subject only had the permanent paraparesis event among the Primary Endpoint components and did not have 12-Month imaging performed).
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) Total(0-546 days)

There have been 12 Aneurysm Subjects (12/74, 16.2%; 83.8% free from endpoint event) that had any primary endpoint event occur**.** Three of these 12 Subjects had more than one type of primary endpoint event: one Subject had device technical success failure and a disabling stroke, another Subject had device technical success failure and two unanticipated additional procedure related to device/procedure at different timepoints, and the third Subject had permanent paraplegia and permanent paraparesis (CEC later removed the permanent paraparesis adjudication).

Aneurysm: Device Technical Success

Device Technical Success was achieved in 91.7% of Subjects in the Aneurysm Cohort. Device Technical Success for all components were reported by each Site investigator.

In the Aneurysm Cohort, seven Subjects (8.3%; 7/84) failed to meet the definition of technical success. As noted earlier, one Subject had two events.

- Four Subjects (4.8%) had device delivery failure (three due to AC not being deployed accurately and one due to delivery system retrieval failure).
- Four Subjects (4.8%) required an unanticipated, additional procedure related to device/procedure (One Subject also had the retrieval failure described above).

The procedure was completed in all Subjects and there were no issues with establishing AC or SB graft patency during the procedure.

Aneurysm Permanent Paraplegia/Paraparesis

There was one Aneurysm Subject (1.2%; 1/84) that has been identified as having permanent paraplegia. This Subject had a site-reported adverse event of spinal cord ischemia on the day of the endovascular procedure, with a SCI scale = 3a at the 1-Month follow-up visit. Although also adjudicated as having permanent paraparesis prior to export, the CEC has since removed the permanent paraparesis adjudication from meeting permanent paraparesis criteria and only meeting the definition for permanent paraplegia.

Two additional Aneurysm Subjects (3.6%) have been identified as having isolated permanent paraparesis:

- One subject had a non-serious adverse event of ‘mild muscle weakness lower limbs’ was reported on POD 11. This was site-reported as unrelated to the device and the procedures. This event is ongoing, and no treatment information has been reported. After data export, the CEC removed this event from meeting permanent paraparesis criteria.
- One Subject had experienced an SAE of ‘spinal cord infarct’ that was reported on POD 1 and was deemed to be related to the endovascular procedure. The event resolved without sequelae on POD 197. The SCI score at the 1-Month follow-up visit = 2.

Aneurysm Unanticipated additional procedure related to device/procedure

There was one Aneurysm Subject (1/84; 1.2%) reported to meet the Protocol definition of having had an unanticipated additional procedure related to device/procedure. This Subject required a reintervention for a Type III endoleak involving the SB Component, occurring on POD 8 and an additional reintervention on POD 420 for a Type III endoleak at the juncture of the proximal aortic extender and aortic component of the TBE device.

Sensitivity Analysis

Table 23 details the pre-specified sensitivity analysis results on the composite Primary Endpoint in the Aneurysm Arm.

The PG was still met in Sensitivity Analysis #1, including the one Subject excluded due to a major selection criteria violation (this person did not have a Primary Endpoint event).

In Sensitivity Analysis #2, the PG was also still met in the worst-case tipping point analysis, where all 10 Subjects excluded were counted as additional Primary Endpoint failures.

Table 23: Sensitivity Analysis on Primary Endpoint Success for Aneurysm Cohort

Primary Endpoint Analysis	Endpoint Denominator	Endpoint Event	Percent Free from Endpoint Event (95% Exact LCL)	Reject Null Hypothesis (LCL > 64% PG)
Sensitivity Analysis #1 Including Major I/E Violation	75	12	84.0% (75.4%)	Yes
Sensitivity Analysis #2 Tipping Point Including Those Missing 12-Month Imaging[1]	84	22	73.8% (64.8%)	Yes

[1]This analysis is based on including those dropped from denominator due to no 12 Month imaging one-by-one as failures and checking at what point the hypothesis conclusion changes.
NOTE: 95% LCL represents one-sided 95% Lower Confidence Limit by exact method.

2. Primary Endpoint Composite: Dissection, Traumatic Transection and Other Isolated Lesions and Procedural Success and Treatment Success for All Cohorts

Table 24: Primary Endpoint Composite Success for Dissection, Traumatic Transection and Other Isolated Lesions Cohorts

Primary Endpoint Analysis	Endpoint Denominator[1]	Endpoint Event	Percent Free from Endpoint Event
Dissection	103	12	88.3%
Traumatic Transection	6	0	100%
Other Isolated Lesion	8	1	87.5%

[1]Primary Endpoint composite (Through 12 Months) denominator is restricted to those with primary endpoint event or 12 Month imaging performed. There has been one Subject excluded from this analysis due to having a CEC-adjudicated major inclusion/exclusion criteria violation one Subject in this cohort has been excluded from all analysis

Dissection Cohort: Primary Endpoint Composite

Table 25: Primary Endpoint Component Events for Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	Total (Through 12 Months)
Number of Enrolled Subjects	132	132	128	125	114	132
Number of Subjects with Imaging in Follow-Up Window	-	17	109	109	98	124
Number of Subjects with Imaging or Primary Endpoint Event in Window	-	18	110	109	98	127
Subjects with Primary Endpoint Event Below[1]	4/132 (3.0%)	2/18 (11.1%)	2/110 (1.8%)	4/109 (3.7%)	0/98 (0%)	12/103 (11.7%)
Device technical success failure[2]	3/132 (2.3%)	-	-	-	-	3/132 (2.3%)
Access or Device Delivery failure	2/132 (1.5%)	-	-	-	-	-
Access failure	0/132 (0%)	-	-	-	-	-
Accurate deployment failure	2/132 (1.5%)	-	-	-	-	-
Device delivery system retrieval failure	0/132 (0%)	-	-	-	-	-
Patency failure	0/132 (0%)	-	-	-	-	-
Unanticipated additional procedure related to device/procedure	3/132 (2.3%)	-	-	-	-	-
Aortic rupture	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	1/132 (0.8%)
Lesion-related mortality	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	1/125 (0.8%)	0/114 (0%)	3/132 (2.3%)
Disabling stroke[2]	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	-	-	1/132 (0.8%)
Permanent paraplegia[2]	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	0/132 (0%)
Permanent paraparesis[2]	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	0/132 (0%)
New onset renal failure requiring permanent dialysis[2]	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	0/132 (0%)
Unanticipated additional procedure related to device/procedure (Protocol-Defined Reintervention)	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	4/125 (3.2%)	0/114 (0%)	6/132 (4.5%)

[1]Primary Endpoint composite denominator is restricted to Subjects either with a primary endpoint event within window and/or imaging done in window. Primary Endpoint Component Event Rates are based on all enrolled subjects.
Primary Endpoint composite Total (Through 12 Months) denominator is further restricted to primary endpoint event in timeframe (i.e. anytime ≤ 546 days; exceptions indicated with a '-'per Protocol definitions) and/or imaging done in 12 Month window (243-546).
[2]Device technical failure events on day 0 only, others are events with onset through day 30.
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) Total(0-546 days)

Traumatic Transection Cohort: Primary Endpoint Composite

There have not been any Traumatic Transection Subjects that had any primary endpoint event occur (6/6, 100% free from endpoint event)**.** One Subject in this cohort was excluded from all analysis.

Other Isolated Lesion Cohort: Primary Endpoint Composite

There has been one Other Isolated Lesion Subject (1/8, 12.5%; 87.5% free from endpoint event) that had any primary endpoint event occur. This Subject had two types of primary endpoint events – aortic rupture and lesion-related mortality. This Subject (underlying pathology was IMH) had a reported adverse event of "Aortic Aneurysm Rupture" (since the date of export, the adverse event description has been updated to "New stent induced entry tear with Aortic Aneurysm Rupture") on POD 534 and was planned to have a reintervention with stent placement later in the week. However, the Subject died due to aortic rupture prior to treatment.

Success Outcomes and Other Outcomes

In addition to the Primary Endpoints noted above, Procedural and Treatment Success data (aggregate and components) were collected and analyzed for all cohorts. Definitions of outcomes are presented in Section X (A) (3).

Procedural Success - All Cohorts

Table 26: Procedural Success through 1 Month[1] for Aneurysm Cohort

	Zone 2 Aneurysm
Number of Enrolled Subjects	84
Subjects with Procedural Success[3]	62 (73.8%)
Procedural Success Events Breakdown	
Site-Reported Outcomes	
Device technical success failure[2]	7 (8.3%)
Death[2]	0 (0%)
Adverse Event or Treatment with CEC Adjudicated Outcomes	
Disabling stroke[2]	3 (3.6%)
Paraplegia[2]	1 (1.2%)
Paraparesis[2,3]	3 (3.6%)
New onset renal failure requiring permanent dialysis[2]	0 (0%)
Unanticipated additional procedure related to device/procedure	1 (1.2%)
New ischemia	0 (0%)
Distal device-related thromboembolic event requiring intervention	0 (0%)
Life-threatening bleed[2]	6 (7.1%)
Myocardial infarction[2]	1 (1.2%)
Prolonged intubation	1 (1.2%)
Laryngeal or phrenic nerve injury[2]	0 (0%)
Renal dysfunction or volume overload requiring ultrafiltration	0 (0%)
Severe heart failure/hypotension	3 (3.6%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes	
Aortic rupture[2]	0 (0%)
New dissection	5 (6.0%)

[1]Day 0-59 unless otherwise noted. Definitions for all events are in Protocol Section 3.4.3.
[2]Device technical failure events on day 0 only, others are events with onset through day 30.
[3]One Subject had been CEC-adjudicated as having both Permanent paraplegia and permanent paraparesis. The CEC adjudication data has since been updated to reflect only having permanent paraplegia. A second Subject had a Site reported non-serious adverse event of 'mild muscle weakness' reported. CEC data has since been updated and this no longer meets the definition of paraparesis. This would result in a paraparesis rate of 1.2% (1/84) and a change in the Procedural Success rate to 75.0% (63/84; the second only had the paraparesis event among the Procedural Success components).

Table 27: Procedural Success through 1 Month for Dissection Cohort

	Zone 2 Dissection
Number of Enrolled Subjects	132
Subjects with Procedural Success	110 (83.3%)

	Zone 2 Dissection
Procedural Success Events Breakdown	
Site-Reported Outcomes	
Device technical success failure[2]	3 (2.3%)
Death[2]	6 (4.5%)
Adverse Event or Treatment with CEC Adjudicated Outcomes	
Disabling stroke[2]	1 (0.8%)
Paraplegia[2]	0 (0%)
Paraparesis[2]	0 (0%)
New onset renal failure requiring permanent dialysis[2]	0 (0%)
Unanticipated additional procedure related to device/procedure	2 (1.5%)
New ischemia	1 (0.8%)
Distal device-related thromboembolic event requiring intervention	0 (0%)
Life-threatening bleed[2]	6 (4.5%)
Myocardial infarction[2]	0 (0%)
Prolonged intubation	1 (0.8%)
Laryngeal or phrenic nerve injury[2]	1 (0.8%)
Renal dysfunction or volume overload requiring ultrafiltration	1 (0.8%)
Severe heart failure/hypotension	0 (0%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes	
Aortic rupture[2]	1 (0.8%)
New dissection	8 (6.1%)
Core Lab Reported Outcomes	
Extension of a dissection[3]	0/110 (0%)

[1]Day 0-59 unless otherwise noted.
[2]Device technical failure events on day 0 only, others are events with onset through day 30.
[3]Denominator further restricted to those with the 'Extension of dissection' Core Lab follow-up assessment known within the time window.

Traumatic Transection Cohort: Procedural Success

Of the nine Traumatic Transection Subjects enrolled and eligible for analysis, 100% have met the definition for Procedural Success.

Other Isolated Lesion Cohort: Procedural Success

Of the 13 Other Isolated Lesion Subjects enrolled and eligible for analysis, 92.3% have met the definition for Procedural Success. There was one Subject (1/13; 7.7%) reported as having a life-threatening bleed within 30 days of the index procedure.

Treatment Success- All Cohorts

Aneurysm and Dissection Results are presented in **Table 28** and **Table 29**. The Treatment Success composite rate for Traumatic Transection and Isolated Lesion was 88.9% (8/9) and 84.6% (11/13) (data tables not presented).

Table 28: Treatment Success by Analysis Study Window for Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	84	84	84	84	80	74	40	6	84
Number of Subjects with Imaging or Event in Window	-	16	73	74	69	53	33	4	84
Subjects with Treatment Success[2,6]	75/84 (89.3%)	9/16 (56.3%)	63/73 (86.3%)	66/74 (89.2%)	64/69 (92.8%)	44/53 (83.0%)	32/33 (97.0%)	4/4 (100.0%)	59/84 (70.2%)
Treatment Success Events Breakdown									
Site-Reported Outcomes[1]									
Device technical success failure	7/84 (8.3%)	-	-	-	-	-	-	-	7/84 (8.3%)
Adverse Event or Treatment with CEC Adjudicated Outcomes[1]									
Lesion-related mortality	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
Disabling stroke (30 days)	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	-	-	-	3/84 (3.6%)
Paraplegia (30 days)	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	-	-	-	-	-	1/84 (1.2%)
Paraparesis (30 days)[6]	1/84 (1.2%)	2/84 (2.4%)	0/84 (0%)	-	-	-	-	-	3/84 (3.6%)
Unanticipated additional procedure related to device/procedure	0/84 (0%)	1/84 (1.2%)	0/84 (0%)	0/84 (0%)	1/80 (1.3%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	1/84 (1.2%)
New ischemia	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes[1]									
Aortic rupture[1]	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
Loss of patency[4]	0/84 (0%)	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/67 (0%)	0/51 (0%)	0/27 (0%)	0/1 (0%)	0/84 (0%)
Fistula formation[1,3]	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/84 (0%)	0/80 (0%)	0/74 (0%)	0/40 (0%)	0/6 (0%)	0/84 (0%)
New dissection[4]	0/84 (0%)	2/13 (15.4%)	3/66 (4.5%)	2/71 (2.8%)	0/64 (0%)	0/51 (0%)	0/26 (0%)	0/1 (0%)	7/84 (8.3%)
Core Lab Reported Outcomes[4]									
Evaluable Subjects	0	13	73	74	69	53	33	4	84
Type I or III Endoleak	-	1/12 (8.3%)	7/69 (10.1%)	6/72 (8.3%)	5/66 (7.6%)	5/51 (9.8%)	0/26 (0%)	0/1 (0%)	8/82 (9.8%)
Loss of device integrity[5]	-	0/13 (0%)	0/71 (0%)	0/71 (0%)	0/66 (0%)	0/53 (0%)	0/28 (0%)	0/1 (0%)	0/84 (0%)
Device migration	-	-	-	0/73 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	0/1 (0%)	0/78 (0%)
Aortic enlargement	-	-	-	1/62 (1.6%)	0/57 (0%)	4/47 (8.5%)	1/25 (4.0%)	0/1 (0%)	4/66 (6.1%)

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total

[1]Denominator is restricted to those at risk at the start of each interval.
[2]Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window (except Endovascular Procedure is among all enrolled).
[3]Doesn't have to be adjudicated.
[4]Denominator further restricted to those with an event or Core Lab assessment known within the window (except Endovascular Procedure is among all enrolled). Absence of a denominator indicates no patients were assessed.
[5]This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events.
[6]One Subject had been CEC-adjudicated as having both Permanent paraplegia and permanent paraparesis. The CEC adjudication data has since been updated to reflect only having permanent paraplegia. A second Subject had a Site reported non-serious adverse event of 'mild muscle weakness' reported. CEC data has since been updated and this no longer meets the definition of paraparesis. This would result in a paraparesis rate of 1.2% (1/84) and a change in the Treatment Success rate to 71.4% (60/84; the second Subject only had the paraparesis event among the Treatment Success components).

Study period definitions: Procedure (0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Table 29: Treatment Success by Analysis Study Window for Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	132	132	128	125	114	85	41	8	132
Number of Subjects with Imaging or Event in Window	-	19	110	109	98	68	32	6	127
Subjects with Treatment Success[2]	127/132 (96.2%)	13/19 (68.4%)	101/110 (91.8%)	99/109 (90.8%)	88/98 (89.8%)	67/68 (98.5%)	32/32 (100.0%)	4/6 (66.7%)	92/127 (72.4%)
Treatment Success Events Breakdown									
Site-Reported Outcomes[1]									
Device technical success failure	3/132 (2.3%)	-	-	-	-	-	-	-	3/132 (2.3%)
Adverse Event or Treatment with CEC Adjudicated Outcomes[1]									
Lesion-related mortality	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	1/125 (0.8%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	3/132 (2.3%)
Disabling stroke (30 days)	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	-	-	-	-	-	1/132 (0.8%)
Paraplegia (30 days)	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	-	-	-	0/132 (0%)
Paraparesis (30 days)	0/132 (0%)	0/132 (0%)	0/128 (0%)	-	-	-	-	-	0/132 (0%)
Unanticipated additional procedure related to device/procedure	0/132 (0%)	1/132 (0.8%)	1/128 (0.8%)	4/125 (3.2%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	6/132 (4.5%)
New ischemia	0/132 (0%)	1/132 (0.8%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	1/132 (0.8%)

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Adverse Event with CEC Adjudicated or Core Lab Reported Outcomes[1]									
Aortic rupture[1]	1/132 (0.8%)	0/132 (0%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	1/132 (0.8%)
Loss of patency[4]	0/132 (0%)	0/17 (0%)	0/107 (0%)	0/106 (0%)	1/96 (1.0%)	0/61 (0%)	0/25 (0%)	0/4 (0%)	1/132 (0.8%)
Fistula formation[1,3]	0/132 (0%)	0/132 (0%)	0/128 (0%)	0/125 (0%)	0/114 (0%)	0/85 (0%)	0/41 (0%)	0/8 (0%)	0/132 (0%)
New dissection[4]	1/132 (0.8%)	4/18 (22.2%)	4/107 (3.7%)	2/104 (1.9%)	4/95 (4.2%)	0/59 (0%)	0/24 (0%)	1/4 (25.0%)	15/132 (11.4%)
Core Lab Reported Outcomes[4]									
Evaluable Subjects	0	17	109	109	98	68	32	6	124
Type I or III Endoleak	-	1/17 (5.9%)	4/106 (3.8%)	2/103 (1.9%)	2/94 (2.1%)	0/60 (0%)	0/25 (0%)	0/4 (0%)	5/122 (4.1%)
Loss of device integrity[5]	-	0/17 (0%)	0/104 (0%)	0/102 (0%)	0/93 (0%)	0/60 (0%)	0/28 (0%)	0/4 (0%)	0/121 (0%)
Device migration	-	-	-	0/107 (0%)	0/97 (0%)	0/64 (0%)	0/29 (0%)	0/4 (0%)	0/117 (0%)
Aortic enlargement	-	-	-	3/95 (3.2%)	3/90 (3.3%)	1/59 (1.7%)	0/29 (0%)	1/3 (33.3%)	6/105 (5.7%)
Extension of dissection (Dissection cohort only)	-	0/15 (0%)	0/107 (0%)	1/103 (1.0%)	0/94 (0%)	0/60 (0%)	0/24 (0%)	0/4 (0%)	1/123 (0.8%)
False lumen perfusion through primary entry tear (Dissection cohort only)	-	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	0/29 (0%)	0/4 (0%)	0/123 (0%)
False lumen perfusion through an aortic arch branch vessel (Dissection cohort only)	-	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)

[1]Denominator is restricted to those at risk at the start of each interval.
[2]Treatment Success composite denominator is restricted to Subjects either with an event within window and/or imaging done in window (except Endovascular Procedure is among all enrolled).
[3]Doesn't have to be adjudicated.
[4]Denominator further restricted to those with an event or Core Lab assessment known within the window (except Endovascular Procedure is among all enrolled).
[5]This component is a combination of Sealing Stent Row Wire Fracture and/or Compression/Invagination events.
Study period definitions: Endovascular Procedure (0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total (0-2006 days)

Traumatic Transection Cohort: Treatment Success

Of the nine Traumatic Transection Subjects enrolled and eligible for analysis, 88.9% of the Subjects have met the definition of Treatment Success as of the data export (those still in study are in the 24-Month follow-up window or later). One Subject (11.1%) failed to meet the definition of Treatment Success due to loss of patency. This Subject experienced an occlusion of the left subclavian artery stent (SB Component) on POD 176. The Site reported this adverse event as non-serious and related to the device. No treatment has been administered to date.

Other Isolated Lesion Cohort: Treatment Success

Of the 13 Other Isolated Lesion Subjects enrolled and eligible for analysis, 84.6% of the Subjects have met the definition of Treatment Success as of the data export (those still in study are in the 24-Month follow-up window or later). Two Other Isolated Lesion Subjects (15.4%) have failed to meet the definition of Treatment Success (one Subject due to lesion-related mortality and aortic rupture on POD 534, and one Subject due to new dissection on POD 203).

Key Events – All Cohorts

Life Threatening Bleed

There were six (7.1%) Aneurysm Subjects reported as having a life-threatening bleed within 30 days of the index procedure. Of these subjects, four a serious access issue (all iliac artery ruptures) at procedure.

There were six Dissection Subjects (4.5%) reported as having a life-threatening bleed within 30 days of the index procedure. Four of the Subjects were affiliated with a serious access issue. Two Subjects experienced iliac artery ruptures and one Patient a groin hematoma. In addition, one Subject experienced a serious femoral pseudoaneurysm. The other two Patients with a life-threatening bleed were results of an aortic rupture and gastrointestinal (GI) hemorrhage (not access-related). Among these six Patients, none required Protocol-defined reinterventions within 1 Month; two died within 30 days of their procedure (the Patient with the GI hemorrhage died of their bleed on POD 2 and the Patient with the groin hematoma died of an embolic stroke on POD 2).

There were no Traumatic Transection Subjects with a reported life-threatening bleed within 30 days of the index procedure.

There was one Other Isolated Lesion Subject (1/13; 7.7%) reported as having a life-threatening bleed within 30 days of the index procedure. This Subject experienced a life-threatening bleed affiliated with a serious access issue (iliac artery rupture) at procedure. The event was resolved without sequelae during the procedure with the deployment of two GORE® VIABAHN® Endoprostheses, and the Subject has since not required any additional unanticipated procedure.

Stroke

Seven (8.3%) Aneurysm Subjects had stroke events adjudicated by the CEC neurologist/OMA as meeting the WHO criteria. Four of these Subjects had WHO strokes within 30 days (three meeting the Primary Endpoint Disabling Stroke criteria) and three Subjects had a WHO stroke after 30-Days.

Seven (5.3%) Dissection Subjects had stroke events adjudicated by the CEC neurologist/OMA as meeting the WHO criteria. Two of these Subjects had WHO strokes within 30 days (one meeting the Primary Endpoint Disabling Stroke criteria) and five Subjects had a WHO stroke after 30 days.

Aneurysm and Dissection Cohort events are summarized in Table 30 and Table 31.

No Traumatic Transection Subjects and one Other Isolated Lesion Subject (7.7%) had a stroke event adjudicated by the neurologist as meeting the WHO criteria. This Subject's WHO stroke was after 30 days.

Table 30: CEC Neurologist/OMA-Adjudicated Strokes by Absolute Study Window for Aneurysm Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	84	84	81	78	65	25	3	84
Subjects with any WHO Stroke or Disabling Stroke	4 (4.8%)	2 (2.4%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	7 (8.3%)
Subjects with WHO Stroke	4 (4.8%)	2 (2.4%)	0 (0%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	7 (8.3%)
Subjects with Disabling Stroke	3 (3.6%)	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (4.8%)

[1]Column header counts and denominators are the number of Subjects at risk at the start of each interval.
Study period definitions: 30 Days(0-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years(732-1096 days) 4 Years(1097-1461 days) 5 Years(1462-1826 days) Total(0-1826 days)

Table 31: CEC Neurologist/OMA-Adjudicated Strokes by Absolute Study Window for Dissection Cohort

	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Total
Number of Enrolled Subjects[1]	132	126	118	109	67	28	1	132
Subjects with any WHO Stroke or Disabling Stroke	2 (1.5%)	1 (0.8%)	1 (0.8%)	2 (1.8%)	1 (1.5%)	0 (0%)	0 (0%)	7 (5.3%)
Subjects with WHO Stroke	2 (1.5%)	1 (0.8%)	1 (0.8%)	2 (1.8%)	1 (1.5%)	0 (0%)	0 (0%)	7 (5.3%)
Subjects with Disabling Stroke	1 (0.8%)	0 (0%)	1 (0.8%)	1 (0.9%)	0 (0%)	0 (0%)	0 (0%)	3 (2.3%)

[1]Column header counts and denominators are the number of Subjects at risk at the start of each interval.
Study period definitions: 30 days(0-30 days) 6 Months(31-182 days) 1 Year(183-365 days) 2 Years(366-731 days) 3 Years (731-1096 days) 4 Years(1097 -1461 days) 5 Years(1462 -1826 days)

New Dissections

Seven (8.3%) Aneurysm Subjects had a new dissection. The location for the new dissection has varied as follows: one Subject (1.2%) in the treated branch (untreated segment), one Subject (1.2%) in the proximal aorta (treated segment), and five Subjects (6.0%) in the distal aorta (treated segment). There were no new dissections reported for untreated branches.

Fifteen Dissection Subjects (11.4%) have had a new dissection. The location for the new dissection has varied as follows: six Subjects (4.5%) in the treated branch (five in the untreated segment; one within treated segment) and nine Subjects (6.8%) in the proximal aorta (two in the untreated segment; seven within treated segment).

No Traumatic Transection Subjects and two Other Isolated Lesion Subjects had a new dissection. The location of the new dissection for both Subjects was the distal aorta (one inside the treated area; one outside the treated area).

Eleven Subjects underwent a reintervention: eight Subjects underwent an open repair, one Subject had an additional stent placed, and two Subjects were treated with drug therapy. Two Subjects died due to their new dissection prior to treatment.

Lesion related Mortality:

There were no Aneurysm Subjects (0%; 0/84) that died that met the definition of lesion-related mortality within the 12-Month follow-up timeframe.

There were three Dissection Subjects (2.3%; 3/132) that died and met the definition of lesion-related mortality through the 12-Month follow-up timeframe.

- Subject died from cardiac arrest on POD 25 (no further details are known and site-reported relationship to devices and procedure is unknown).
- Subject died from cardiac tamponade due to ruptured aortic dissection in the ascending aorta (outside of the treated segment) on POD 6.
- Subject died from cardiac arrest on POD 79 after undergoing surgical reintervention for an ascending aortic dissection on POD 77.

There were no Traumatic Transection Subjects (0%; 0/9) that died that met the definition of lesion-related mortality within the 12-Month follow-up timeframe.

There was one Other Isolated Lesion Subject who died from aortic aneurysm rupture on POD 534. This Subject is fully discussed in the Other Isolated Lesion Primary Composite Endpoint discussion.

Endoleaks

For the Aneurysm Cohort, 78.6% of Subjects were free from any type of Site-reported endoleak. **Table 32** summarizes the Site Reported Endoleaks by Study Period.
Six Aneurysm Subjects (7.1%) had Type IA endoleaks reported. Four of these endoleaks were reported during the procedure and the other two occurred at other times throughout follow-up. No Site-reported adverse events of aortic enlargement have been reported for any of the Type IA endoleaks. Two Subjects (2.4%) have required treatment for the Type IA endoleaks:

- One Subject– Type IA endoleak noted during the procedure, requiring balloon angioplasty at the proximal landing zone.
- One Subject– Type IA endoleak noted on POD 766 which was treated with stents to successfully resolve the endoleak.

The Subject with the Type IA endoleak on POD 766 also had one Type IB endoleak reported and treated with a stent on POD 3 (no Site-reported adverse events for aortic enlargement have been reported for this Subject). However, this endoleak was an iliac endoleak related to a previous abdominal aortic procedure and was not related to the GORE® TAG® Thoracic Branch Endoprosthesis.

Nine Subjects (10.7%) had a Site-reported Type II endoleak. There have been no Site-reported treatments for these endoleaks. Two Subjects (2.4%) had a Site-reported Type III endoleak and one Subject required treatment.

Table 32: Site-Reported Endoleaks by Analysis Study Window for Zone 2 Aneurysm Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Subjects[1]	84	84	84	84	80	74	40	6	84
Evaluable Subjects[2]	84	19	74	76	72	55	33	4	84
Subjects With One or More Endoleak Ongoing in Window	7 (8.3%)	10 (52.6%)	15 (20.3%)	13 (17.1%)	11 (15.3%)	9 (16.4%)	2 (6.1%)	0 (0%)	18 (21.4%)
New	7 (8.3%)	3 (15.8%)	9 (12.2%)	1 (1.3%)	1 (1.4%)	1 (1.8%)	0 (0%)	-	-
Ongoing	-	7 (36.8%)	7 (9.5%)	12 (15.8%)	11 (15.3%)	8 (14.5%)	2 (6.1%)	-	-
Type I	4 (4.8%)	5 (26.3%)	5 (6.8%)	2 (2.6%)	2 (2.8%)	3 (5.5%)	0 (0%)	0 (0%)	6 (7.1%)
New	4 (4.8%)	1 (5.3%)	1 (1.4%)	0 (0%)	0 (0%)	1 (1.8%)	-	-	-
Type IA	4 (4.8%)	0 (0%)	1 (1.4%)	-	-	1 (1.8%)	-	-	6 (7.1%)
Type IB	0 (0%)	1 (5.3%)[3]	0 (0%)	-	-	0 (0%)	-	-	1 (1.2%)[3]
Type IC	0 (0%)	0 (0%)	0 (0%)	-	-	0 (0%)	-	-	0 (0%)
Ongoing	-	4 (21.1%)	4 (5.4%)	2 (2.6%)	2 (2.8%)	2 (3.6%)	-	-	-
Type II	1 (1.2%)	3 (15.8%)	7 (9.5%)	7 (9.2%)	5 (6.9%)	3 (5.5%)	1 (3.0%)	0 (0%)	9 (10.7%)
New	1 (1.2%)	2 (10.5%)	5 (6.8%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	-	-
Ongoing	-	1 (5.3%)	2 (2.7%)	6 (7.9%)	5 (6.9%)	3 (5.5%)	1 (3.0%)	-	-
Type III	1 (1.2%)	1 (5.3%)	2 (2.7%)	2 (2.6%)	2 (2.8%)	1 (1.8%)	1 (3.0%)	0 (0%)	2 (2.4%)
New	1 (1.2%)	0 (0%)	2 (2.7%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	-	-
Type IIIA	0 (0%)	-	0 (0%)	-	1 (1.4%)	-	-	-	1 (1.2%)
Type IIIB	0 (0%)	-	0 (0%)	-	0 (0%)	-	-	-	0 (0%)
Type III Indeterminate	1 (1.2%)	-	2 (2.7%)	-	0 (0%)	-	-	-	2 (2.4%)
Ongoing	-	1 (5.3%)	0 (0%)	2 (2.6%)	2 (2.8%)	1 (1.8%)	1 (3.0%)	-	-
Indeterminate	1 (1.2%)	1 (5.3%)	2 (2.7%)	2 (2.6%)	2 (2.8%)	2 (3.6%)	0 (0%)	0 (0%)	2 (2.4%)
New	1 (1.2%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	0 (0%)	-	-	-
Ongoing	-	1 (5.3%)	1 (1.4%)	2 (2.6%)	2 (2.8%)	2 (3.6%)	-	-	-
Subjects With No Endoleak Ongoing in Window	77 (91.7%)	9 (47.4%)	59 (79.7%)	63 (82.9%)	61 (84.7%)	46 (83.6%)	31 (93.9%)	4 (100.0%)	66 (78.6%)

[1]Column header counts are the number of subjects at risk at the start of each interval.
[2]Denominators are the number of evaluable subjects (subject had either CT or MR done in window or ongoing endoleak at each interval). All included subjects who initiated Endovascular Procedure are counted in the denominator in the Procedure and Total columns.
[3]This Subject reported a Type IB endoleak but it was not related to the GORE® TAG® Thoracic Branch Endoprosthesis; it was related to an abdominal aortic endovascular device previously implanted.
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Core Lab identified three Aneurysm Subjects (3.7%) with Type I endoleaks at any timepoint, 21 Subjects (25.6%) with Type II endoleaks, and five Subjects (6.1%) with Type III endoleaks.

Three Subjects with reported aortic enlargement also had endoleaks reported by the Core Lab (two Subjects with a reported Type II endoleak and one Subject with a Type III endoleak). **Table 33** summarizes the Core Lab device event findings by study period.

Table 33: Core Lab Device Event Findings by Analysis Study Window for Zone 2 Aneurysm Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	84	84	84	80	74	40	6	84
Evaluable Subjects[2]	13	73	74	69	53	33	4	84

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Subjects with any below device event finding in window	6/13 (46.2%)	27/73 (37.0%)	24/74 (32.4%)	21/69 (30.4%)	13/53 (24.5%)	2/33 (6.1%)	0/4 (0%)	36/84 (42.9%)
Device event findings								
Endoleak	6/12 (50.0%)	27/69 (39.1%)	24/72 (33.3%)	21/66 (31.8%)	13/51 (25.5%)	2/26 (7.7%)	-	36/82 (43.9%)
Type I	0/12 (0%)	2/69 (2.9%)	3/72 (4.2%)	3/66 (4.5%)	3/51 (5.9%)	0/26 (0%)	-	3/82 (3.7%)
Type IA	-	1/69 (1.4%)	2/72 (2.8%)	2/66 (3.0%)	2/51 (3.9%)	-	-	2/82 (2.4%)
Type IB	-	1/69 (1.4%)	1/72 (1.4%)	1/66 (1.5%)	1/51 (2.0%)	-	-	1/82 (1.2%)
Type IC	-	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type II	3/12 (25.0%)	13/69 (18.8%)	13/72 (18.1%)	14/66 (21.2%)	8/51 (15.7%)	1/26 (3.8%)	-	21/82 (25.6%)
Type III	1/12 (8.3%)	5/69 (7.2%)	3/72 (4.2%)	2/66 (3.0%)	2/51 (3.9%)	0/26 (0%)	-	5/82 (6.1%)
Type IIIA	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type IIIA involving SB	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type IIIB	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	-	-	0/82 (0%)
Type III Indeterminate	1/12 (8.3%)	5/69 (7.2%)	3/72 (4.2%)	2/66 (3.0%)	2/51 (3.9%)	-	-	5/82 (6.1%)
Type III Indeterminate involving SB	0/12 (0%)	3/69 (4.3%)	1/72 (1.4%)	1/66 (1.5%)	1/51 (2.0%)	-	-	3/82 (3.7%)
Type IV	0/12 (0%)	0/69 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	0/26 (0%)	-	0/82 (0%)
Indeterminate	1/12 (8.3%)	9/69 (13.0%)	7/72 (9.7%)	4/66 (6.1%)	3/51 (5.9%)	1/26 (3.8%)	-	19/82 (23.2%)
Aortic Device Loss of Patency	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/67 (0%)	0/51 (0%)	0/27 (0%)	-	0/82 (0%)
SB Loss of Patency	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/67 (0%)	0/51 (0%)	0/27 (0%)	-	0/82 (0%)
Aortic Rupture	0/13 (0%)	0/70 (0%)	0/72 (0%)	0/66 (0%)	0/51 (0%)	0/26 (0%)	-	0/83 (0%)
Device Migration	0/13 (0%)	0/72 (0%)	0/73 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Wire Fracture	0/13 (0%)	0/72 (0%)	0/73 (0%)	0/66 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Extrusion/Erosion	0/13 (0%)	0/72 (0%)	0/74 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Device Compression/Invagination	0/13 (0%)	0/72 (0%)	0/74 (0%)	0/67 (0%)	0/53 (0%)	0/28 (0%)	-	0/84 (0%)
Other anatomical findings								
Aortic Enlargement (≥ 5mm)[3]	-	-	1/62 (1.6%)	0/57 (0%)	4/47 (8.5%)	1/25 (4.0%)	0/1 (0%)	4/66 (6.1%)

[1]Column header counts are the number of subjects at risk at the start of each interval.
[2]Denominators for each device finding category time window are the number of evaluable subjects (subject had either CT or MR done in window) with a known evaluation in each window.
[3]Aortic enlargement is based on Maximum Transverse Diameter of Aneurysm. Subjects evaluated for change from baseline are those subjects that have both a baseline measurement and a measurement in each follow-up time window. If there is more than one non-missing measurement in a time window, the largest (worst) aneurysm diameter is kept for analysis.
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

For the Dissection Cohort 89.4% of Subjects were free from any type of Site-reported endoleak. **Table 34** summarizes the Site Reported Endoleaks by Study Period.

Four Subjects (3.0%) had Type IA endoleaks. Three of these endoleaks were reported during the procedure and the other one occurred during the 1-Month absolute window. No Site-reported adverse events of aortic enlargement have been reported for any of the Type IA endoleaks. Two Subjects (1.5%) have required treatment for the Type IA endoleaks.

- One Subject– Type IA endoleak noted on POD 32, requiring embolization on POD 145.
- One Subject– Type IA endoleak noted during the procedure, requiring thoracic stent graft placement on POD 84.

Three Subjects had a Site-reported Type IB endoleak. One Subject required treatment for the Type IB endoleak with a thoracic aortic stent graft placed on POD 253. No Site-reported adverse events of aortic enlargement have been reported for any of the Type IB endoleaks.

Eight Subjects (6.1%) had a Type II endoleak reported. Of the eight Subjects with reported Type II endoleaks, one Subject required treatment on POD 1159 (drug therapy) and POD 1162 (thoracic stent graft placement with embolization).

One Subject (0.8%) had a Type III endoleak reported. No treatment has been reported for this Subject.

Table 34: Site-Reported Endoleaks by Analysis Study Window for Zone 2 Dissection Cohort

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Subjects[1]	132	132	128	125	114	85	41	8	132
Evaluable Subjects[2]	132	24	110	110	99	68	33	6	132
Subjects With One or More Endoleak Ongoing in Window	3 (2.3%)	8 (33.3%)	12 (10.9%)	10 (9.1%)	9 (9.1%)	4 (5.9%)	4 (12.1%)	1 (16.7%)	14 (10.6%)
New	3 (2.3%)	5 (20.8%)	4 (3.6%)	1 (0.9%)	1 (1.0%)	0 (0%)	1 (3.0%)	0 (0%)	-
Ongoing	-	3 (12.5%)	8 (7.3%)	9 (8.2%)	8 (8.1%)	4 (5.9%)	3 (9.1%)	1 (16.7%)	-
Type I	3 (2.3%)	5 (20.8%)	6 (5.5%)	5 (4.5%)	3 (3.0%)	0 (0%)	0 (0%)	0 (0%)	7 (5.3%)
New	3 (2.3%)	2 (8.3%)	1 (0.9%)	1 (0.9%)	0 (0%)	-	-	-	-
Type IA	3 (2.3%)	0 (0%)	1 (0.9%)	0 (0%)	-	-	-	-	4 (3.0%)
Type IB	0 (0%)	2 (8.3%)	0 (0%)	1 (0.9%)	-	-	-	-	3 (2.3%)
Type IC	0 (0%)	0 (0%)	0 (0%)	0 (0%)	-	-	-	-	0 (0%)
Ongoing	-	3 (12.5%)	5 (4.5%)	4 (3.6%)	3 (3.0%)	-	-	-	-
Type II	0 (0%)	3 (12.5%)	6 (5.5%)	4 (3.6%)	5 (5.1%)	4 (5.9%)	4 (12.1%)	1 (16.7%)	8 (6.1%)
New	-	3 (12.5%)	3 (2.7%)	0 (0%)	1 (1.0%)	0 (0%)	1 (3.0%)	0 (0%)	-
Innominate	-	0 (0%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
LCCA	-	0 (0%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
LSA[3]	-	0 (0%)	1 (33.3%)	-	0 (0%)	-	0 (0%)	-	-
Vertebral	-	1 (33.3%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
Intercostal	-	1 (33.3%)	1 (33.3%)	-	0 (0%)	-	0 (0%)	-	-
Bronchials	-	0 (0%)	0 (0%)	-	0 (0%)	-	0 (0%)	-	-
Other	-	1 (33.3%)	1 (33.3%)	-	1 (100.0%)	-	1 (100.0%)	-	-
Ongoing	-	0 (0%)	3 (2.7%)	4 (3.6%)	4 (4.0%)	4 (5.9%)	3 (9.1%)	1 (16.7%)	-
Source (Dissection cohort only)									
Type III	0 (0%)	1 (4.2%)	1 (0.9%)	1 (0.9%)	1 (1.0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.8%)
New	-	1 (4.2%)	0 (0%)	0 (0%)	0 (0%)	-	-	-	-
Type IIIA	-	0 (0%)	-	-	-	-	-	-	0 (0%)
Type IIIB	-	0 (0%)	-	-	-	-	-	-	0 (0%)
Type III Indeterminate	-	1 (4.2%)	-	-	-	-	-	-	1 (0.8%)
Ongoing	-	0 (0%)	1 (0.9%)	1 (0.9%)	1 (1.0%)	-	-	-	-
Indeterminate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
New	-	-	-	-	-	-	-	-	-
Ongoing	-	-	-	-	-	-	-	-	-
Subjects With No Endoleak Ongoing in Window	129 (97.7%)	16 (66.7%)	98 (89.1%)	100 (90.9%)	90 (90.9%)	64 (94.1%)	29 (87.9%)	5 (83.3%)	118 (89.4%)

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total

[1]Column header counts are the number of subjects at risk at the start of each interval.

[2]Denominators are the number of evaluable subjects (subject had either CT or MR done in window or ongoing endoleak at each interval). All included subjects who initiated Endovascular Procedure are counted in the denominator in the Procedure and Total columns.

Study period definitions: Endovascular Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total (0-2006 days)

[3]Upcon further review of the Type II endoleak in the LSA, the Site PI for Subject 1102-192-117 has determined this to be a data entry error and no endoleak is present.The database has since been updated to reflect this information.

Core Lab identified three (2.5%) Subjects with Type I endoleaks at any timepoint, 23 (18.9%) Subjects with Type II endoleaks, and in two (1.6%) Subjects with Type III endoleaks.

Two Subjects with reported aortic enlargement also had endoleaks reported by the Core Lab (both indeterminate endoleaks). **Table 35** summarizes the Core Lab device event findings by study period.

Table 35: Core Lab Device Event Findings by Analysis Study Window for Zone 2 Dissection Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Enrolled Subjects[1]	132	128	125	114	85	41	8	132
Evaluable Subjects[2]	17	109	109	98	68	32	6	124
Subjects with any below device event finding in window	3/17 (17.6%)	34/109 (31.2%)	17/109 (15.6%)	16/98 (16.3%)	10/68 (14.7%)	0/32 (0%)	2/6 (33.3%)	47/124 (37.9%)
Device event findings								
Endoleak	3/17 (17.6%)	34/106 (32.1%)	17/103 (16.5%)	15/94 (16.0%)	10/60 (16.7%)	-	2/4 (50.0%)	47/122 (38.5%)
Type I	1/17 (5.9%)	3/106 (2.8%)	1/103 (1.0%)	1/94 (1.1%)	0/60 (0%)	-	0/4 (0%)	3/122 (2.5%)
Type IA	0/17 (0%)	1/106 (0.9%)	0/103 (0%)	0/94 (0%)	-	-	-	1/122 (0.8%)
Type IB	1/17 (5.9%)	2/106 (1.9%)	1/103 (1.0%)	1/94 (1.1%)	-	-	-	2/122 (1.6%)
Type IC	0/17 (0%)	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type II	0/17 (0%)	13/106 (12.3%)	7/103 (6.8%)	5/94 (5.3%)	5/60 (8.3%)	-	1/4 (25.0%)	23/122 (18.9%)
Source (Dissection cohort only)								
Vertebral	-	1/13 (7.7%)	1/7 (14.3%)	0/5 (0%)	0/5 (0%)	-	0/1 (0%)	2/23 (8.7%)
Intercostal	-	12/13 (92.3%)	5/7 (71.4%)	5/5 (100.0%)	4/5 (80.0%)	-	1/1 (100.0%)	19/23 (82.6%)
Bronchials	-	0/13 (0%)	1/7 (14.3%)	0/5 (0%)	0/5 (0%)	-	1/1 (100.0%)	2/23 (8.7%)
Other	-	0/13 (0%)	0/7 (0%)	0/5 (0%)	1/5 (20.0%)	-	0/1 (0%)	1/23 (4.3%)
Type III	0/17 (0%)	1/106 (0.9%)	1/103 (1.0%)	1/94 (1.1%)	0/60 (0%)	-	0/4 (0%)	2/122 (1.6%)
Type IIIA	-	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type IIIA involving SB	-	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type IIIB	-	0/106 (0%)	0/103 (0%)	0/94 (0%)	-	-	-	0/122 (0%)
Type III Indeterminate	-	1/106 (0.9%)	1/103 (1.0%)	1/94 (1.1%)	-	-	-	2/122 (1.6%)
Type III Indeterminate involving SB	-	1/106 (0.9%)	0/103 (0%)	0/94 (0%)	-	-	-	1/122 (0.8%)
Type IV	0/17 (0%)	0/106 (0%)	0/103 (0%)	0/94 (0%)	0/60 (0%)	-	0/4 (0%)	0/122 (0%)
Indeterminate	2/17 (11.8%)	18/106 (17.0%)	10/103 (9.7%)	10/94 (10.6%)	5/60 (8.3%)	-	2/4 (50.0%)	28/122 (23.0%)
Aortic Device Loss of Patency	0/17 (0%)	0/107 (0%)	0/106 (0%)	0/96 (0%)	0/61 (0%)	-	0/4 (0%)	0/123 (0%)

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
SB Loss of Patency	0/16 (0%)	0/107 (0%)	0/106 (0%)	1/95 (1.1%)	0/61 (0%)	-	0/4 (0%)	1/123 (0.8%)
Aortic Rupture	0/17 (0%)	0/107 (0%)	0/105 (0%)	0/96 (0%)	0/61 (0%)	-	0/4 (0%)	0/123 (0%)
Device Migration	0/16 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	-	0/4 (0%)	0/123 (0%)
Wire Fracture	0/17 (0%)	0/104 (0%)	0/102 (0%)	0/94 (0%)	0/60 (0%)	-	0/4 (0%)	0/121 (0%)
Extrusion/Erosion	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	-	0/4 (0%)	0/123 (0%)
Device Compression/Invagination	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	-	0/4 (0%)	0/123 (0%)
Other anatomical findings								
Aortic Enlargement (≥ 5mm)[3]	-	-	3/95 (3.2%)	3/90 (3.3%)	1/59 (1.7%)	0/29 (0%)	1/3 (33.3%)	6/105 (5.7%)

[1]Column header counts are the number of subjects at risk at the start of each interval.
[2]Denominators for each device finding category time window are the number of evaluable subjects (subject had either CT or MR done in window) with a known evaluation in each window.
[3]Aortic enlargement is based on Maximum Aortic Diameter in Treated Segment for Dissection Subjects. Subjects evaluated for change from baseline are those subjects that have both a baseline measurement and a measurement in each follow-up time window. If there is more than one non-missing measurement in a time window, the largest (worst) aneurysm diameter is kept for analysis.
Study period definitions: Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total (1-2006 days)

There have been no Site or Core Lab reported endoleaks for the Traumatic Transection Cohort. A Core Lab identified Type II endoleak has been identified in one Other Isolated Lesion Subject (7.7%); there have been no Site-reported endoleaks for this cohort.

False Lumen Perfusion and False Lumen Status: Dissection Cohort Only

Table 36 provides a summary of false lumen perfusion and false lumen status by follow-up period for Dissection Subjects, as reported by Core Lab. Note that both false lumen perfusion through the primary intimal tear and through an aortic arch branch vessel are Treatment Success components (and are shown as well in **Table 29**). The GORE® TAG® Thoracic Branch Endoprosthesis device was completely successful in negating both of these types of false lumen perfusion.

The majority of the reported false lumen perfusions reported were through a non-aortic arch branch vessel (88.5%).

False lumen perfusion through the proximal aorta was observed in nine Subjects. Eight of these Subjects had a new dissection in the proximal aorta; the other Subject had a Type IA endoleak observed at 1 month (Core Lab reported, no treatment required).

It can be seen that a large majority of Subjects (>80%) experienced this over time. This is not unexpected when considering the majority of Subjects presented with dissections extending distally between Zone 6 and Zone 10/11 (86.7%, among those with distal extent assessable) and the majority of these vessels are outside of the treated segment of aorta and provide the on-going potential to continue perfusing the false lumen. The majority of Subjects (>75%) have a patent or partially thrombosed false lumen in the distal (untreated) aorta. However, it can be seen that the percent of Subjects with complete thrombosis in the distal aorta increases in follow-up while the percentage of Subjects with patent false lumen in the distal aorta decreases in the follow-up.

False lumen status in the treated segment was an additional 'other outcome'. One Subject had no thrombosis in the treated segment in the 24-Month window. The percent of Subjects with complete thrombosis in the treated segment is, in general, increasing in follow-up. For example, 35.8% of Subjects had complete thrombosis at 1-Month and then 55.3% of Subjects had complete thrombosis at 12-Months.

Table 36: Core Lab False Lumen Perfusion and Status by Analysis Study Window for Zone 2 Dissection Cohort

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
Number of Subjects[1]	132	128	125	114	85	41	8	132
Number of Subjects with Imaging[2]	17	109	109	98	68	32	6	124
False Lumen Perfusion through primary intimal tear[3]	0/17 (0%)	0/109 (0%)	0/107 (0%)	0/97 (0%)	0/64 (0%)	0/29 (0%)	0/4 (0%)	0/123 (0%)
False Lumen Status[4,5] - Treated Segment								
Patent	0/17 (0%)	0/106 (0%)	0/104 (0%)	0/94 (0%)	1/61 (1.6%)	0/25 (0%)	0/4 (0%)	1/122 (0.8%)
Partial thrombosis	12/17 (70.6%)	68/106 (64.2%)	53/104 (51.0%)	42/94 (44.7%)	28/61 (45.9%)	8/25 (32.0%)	2/4 (50.0%)	81/122 (66.4%)
Complete thrombosis	5/17 (29.4%)	38/106 (35.8%)	51/104 (49.0%)	52/94 (55.3%)	32/61 (52.5%)	17/25 (68.0%)	2/4 (50.0%)	40/122 (32.8%)
False Lumen Perfusion – Source of Perfusion: Proximal Aorta	1/17 (5.9%)	2/106 (1.9%)	3/104 (2.9%)	4/95 (4.2%)	2/61 (3.3%)	0/25 (0%)	1/4 (25.0%)	9/122 (7.4%)
False Lumen Perfusion through a branch vessel	13/16 (81.3%)	96/106 (90.6%)	88/105 (83.8%)	81/96 (84.4%)	52/61 (85.2%)	21/25 (84.0%)	3/4 (75.0%)	108/123 (87.8%)
Through an Aortic Arch Branch Vessel[3]	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
Innominate	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
LCCA	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
LSA	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
Other	0/16 (0%)	0/106 (0%)	0/104 (0%)	0/96 (0%)	0/60 (0%)	0/25 (0%)	0/3 (0%)	0/123 (0%)
Through a Non-Aortic Arch Branch Vessel[5]	13/16 (81.3%)	96/106 (90.6%)	88/104 (84.6%)	81/95 (85.3%)	52/61 (85.2%)	21/25 (84.0%)	3/4 (75.0%)	108/122 (88.5%)
Celiac	5/16 (31.3%)	25/106 (23.6%)	18/104 (17.3%)	20/95 (21.1%)	12/61 (19.7%)	6/25 (24.0%)	1/4 (25.0%)	32/122 (26.2%)
SMA	2/16 (12.5%)	10/106 (9.4%)	7/104 (6.7%)	10/95 (10.5%)	5/61 (8.2%)	3/25 (12.0%)	0/4 (0%)	13/122 (10.7%)
Right Renal	5/16 (31.3%)	31/106 (29.2%)	31/104 (29.8%)	26/95 (27.4%)	14/61 (23.0%)	3/25 (12.0%)	1/4 (25.0%)	39/122 (32.0%)
Left Renal	9/16 (56.3%)	38/106 (35.8%)	31/104 (29.8%)	28/95 (29.5%)	16/61 (26.2%)	6/25 (24.0%)	1/4 (25.0%)	44/122 (36.1%)
Right Com Iliac	1/16 (6.3%)	5/106 (4.7%)	7/104 (6.7%)	7/95 (7.4%)	5/61 (8.2%)	2/25 (8.0%)	1/4 (25.0%)	12/122 (9.8%)
Left Com Iliac	3/16 (18.8%)	5/106 (4.7%)	11/104 (10.6%)	3/95 (3.2%)	3/61 (4.9%)	2/25 (8.0%)	0/4 (0%)	15/122 (12.3%)
Other[6]	11/16 (68.8%)	91/106 (85.8%)	85/104 (81.7%)	76/95 (80.0%)	51/61 (83.6%)	20/25 (80.0%)	3/4 (75.0%)	103/122 (84.4%)

	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	Total
False Lumen Perfusion – Source of perfusion: Distal Aorta	12/17 (70.6%)	91/106 (85.8%)	83/104 (79.8%)	79/95 (83.2%)	49/61 (80.3%)	21/25 (84.0%)	3/4 (75.0%)	103/122 (84.4%)
False Lumen Status[4,5] – Untreated Aorta								
Patent	8/12 (66.7%)	16/96 (16.7%)	14/90 (15.6%)	10/85 (11.8%)	4/54 (7.4%)	1/23 (4.3%)	0/3 (0%)	29/109 (26.6%)
Partial thrombosis	4/12 (33.3%)	79/96 (82.3%)	72/90 (80.0%)	70/85 (82.4%)	46/54 (85.2%)	20/23 (87.0%)	3/3 (100.0%)	79/109 (72.5%)
Complete thrombosis	0/12 (0%)	1/96 (1.0%)	4/90 (4.4%)	5/85 (5.9%)	4/54 (7.4%)	2/23 (8.7%)	0/3 (0%)	1/109 (0.9%)

[1]Subjects at risk at the start of each interval.
[2]Denominators for each device finding category time window are the number of evaluable subjects (subject had either CT or MR done in window) with a known evaluation in each window.
[3]These are Treatment Success Outcomes.
[4]If there is more than one evaluation for a Subject in a time window, the worst finding is reported for that window (Patent is worst, followed by Partial thrombosis).
[5]These are Other Success Outcomes as described under Section X(A)(3).
[6]Other sources primarily included: intercostal arteries, vertebral arteries, IMA, accessory renal arteries, distal secondary tears, and right/left external iliacs.
Study period definitions: Post-~Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(1-2006 days)

Aortic Enlargement

There were four (6.1%) Aneurysm Subjects with aortic enlargement as assessed by Core Lab. The implanting sites also recorded enlargement for two of these subjects. There have been no reports of aneurysm rupture or unexplained / sudden death for any of these Subjects and no Site-reported additional interventions or treatments have been required.

There were six (5.7%) Subjects with aortic enlargement as assessed by Core Lab in the Dissection cohort. The implanting sites also recorded aortic enlargement for five subjects. One Subject also had a Site-reported adverse event of aneurysm sac enlargement on POD 314 that required a stent. The remaining five Subjects have had no Site-reported aortic rupture, unexplained sudden death or treatments associated with aortic enlargement.

There were no reports of aortic enlargement in the Traumatic Transection or Other Isolated Lesion cohorts.

New Renal Failure requiring dialysis- All Cohorts

There were no new onset renal failure requiring permanent dialysis events reported during the 30-day follow-up window for any of the Subjects in the Aneurysm, Dissection, Traumatic Transection, or Other Isolated Lesion Cohorts.

Unanticipated reinterventions related to device/procedure

There was one Aneurysm Subject (1.2%) who required an unanticipated additional procedure related to device/procedure. This Subject required a reintervention for a Type III endoleak involving the SB Component, occurring on POD 8 and an additional reintervention on POD 420 for a Type III endoleak at the juncture of the proximal aortic extender and aortic component of the TBE device.

Six (4.5%) Dissection Subjects required a reintervention, all occurring within 6-Months of the endovascular procedure.

- One Subject required open total arch replacement on POD 132 due to a retrograde Type A dissection.
- Another Subject had a Type IA endoleak treated with embolization on POD 145 which resolved without sequelae on the same day.
- A Subject underwent aortic root replacement and ascending and transverse aortic arch replacement on POD 77 for treatment of a retrograde aortic dissection extending from the proximal end of the TBE device with onset on POD 76. The Subject died on POD 80 due to cardiac arrest.
- An additional Subject had total aortic arch replacement on POD 13 for treatment of a retrograde aortic dissection with onset on POD 12. The new dissection resolved without sequelae on the same day as treatment.
- A Subject was treated on POD 84 with a thoracic stent for a Type IA endoleak. The endoleak resolved without sequelae on the same day as treatment.
- A Subject underwent open repair of an ascending aortic dissection (distal ascending and proximal transverse thoracic aorta with onset on POD 27) with a hemiarch procedure on POD 45. The new dissection resolved without sequelae on the same day as treatment.

No Traumatic Transection or Other Isolated Lesion Subjects required an unanticipated additional procedure related to device/procedure.

3. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: sex.

Subgroup analysis on the composite Primary Endpoint results for the Aneurysm Cohort was performed by sex. Freedom from a Primary Endpoint event was observed in 85.1% of male Aneurysm Subjects and 81.5% of female Aneurysm Subjects. Based on the statistical test performed, there is no statistically significant difference in the composite Primary Endpoint rate by sex (P-value=0.749).

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and

arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 175 investigators of which 0 were full-time or part-time employees of the sponsor and 7 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payment of other sorts: 7
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

After enrollment was completed in the Aneurysm cohort, continued access was granted. Subjects were followed and reported according to the pivotal study protocol. There were six continued access Subjects enrolled. Among these six Subjects, there was 100% primary endpoint success (including device technical success), 100% procedural success, and 83.3% treatment success (at the time of data export). One Subject had a new dissection event in the 6-Month follow-up. All six Subjects remain in follow-up, with two in the 12-Month window (one had their 12-Month visit) and four in the 24-Month window at the time of data export.

In addition, there were 31 Aneurysm Feasibility Study Subjects enrolled prior to the Pivotal Study. Key outcomes are summarized (Pivotal Study definitions). There was 90.3% device Technical Success. There were no deaths within 30 days. Through 12 months, the lesion-related mortality and aortic rupture rates were 0%, the stroke rate was 3.2%, and 6.5% of Subjects had an unanticipated additional procedure related to device/procedure. The Core Lab reported Type I and III endoleak rates through 12 months were 3.2% and 6.5%, respectively, with no reports of aortic enlargement. There was one (3.2%) patient with loss of SB patency and a different patient (3.2%) with a device compression, through 12 months.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical study conducted to support PMA approval as described above.

The primary composite safety and effectiveness endpoint was analyzed for all study cohorts. The Primary Endpoint was a composite of Device Technical Success (DTS) and absence of aortic rupture, lesion related mortality, disabling stroke, permanent paraplegia, permanent paraparesis, new onset renal failure requiring dialysis and unanticipated additional procedure related to the device/procedure through 12 months. Primary Endpoint success through 12 months was achieved in 83.8% of Aneurysm Subjects (62/74 evaluable Subjects) with a 95% one-sided Exact lower confidence limit of freedom from primary endpoint events of 75.1%. The Aneurysm hypothesis-driven cohort was successful in meeting its performance goal of 64%.

There were no pre-specified statistical hypotheses for the Dissection cohort, Traumatic Transection cohort, or Other Isolated Lesions cohort. However, outcomes were collected and summarized under a unified Study Protocol, similar to the Aneurysm cohort. The following summarizes Primary Endpoint success results for each of these cohorts.

- Dissection cohort: 88.3% (91/103 evaluable Subjects). Two Subjects were still in the 12-Month window.
- Traumatic Transection cohort: 100% (6/6 evaluable Subjects)
- Other Isolated Lesion cohort: 87.5% (7/8 evaluable Subjects)

In addition to the Primary Endpoint, success outcomes were analyzed for all cohorts. Procedural Success through 1 month was the absence of DTS failure and 16 success outcomes (see definitions Section X (A)(3)). Treatment Success

through all follow-up was the absence of DTS failure and 15 success outcomes (see definitions Section X (A) (3)).

Procedural Success results by cohort are as follows:

- Aneurysm cohort: 73.8% (62/84)
- Dissection cohort: 83.3% (110/132)
- Traumatic Transection cohort: 100% (9/9)
- Other Isolated Lesion cohort: 92.3% (12/13)

Treatment Success results by cohort are as follows (note that this is through 5 years, however, follow-up was ongoing):

- Aneurysm cohort: 70.2% (59/84). Sixty-five (65) of the 84 Subjects remained in follow-up and were in the 36-Month or later windows at the time of export.
- Dissection cohort: 72.4% (91/127). One hundred five (105) of the 132 Subjects remained in follow-up and were in the 12-Month or later windows at time of export
- Traumatic Transection cohort: 88,8% (8/9). All Subjects remained in follow-up and were in the 24-Month window at time of export.
- Other Isolated Lesion cohort: 84.6% (11/13). Eight Subjects remained in follow-up and were in the 24-Month or later windows at time of export.

Device Technical Success was achieved in 95.8% of the Subjects (all cohorts).

During the execution of the clinical study, the following outcome event rates, shown in **Table 37,** were reported and may be higher than corresponding rates reported for non-branched TEVAR. These outcomes need to be considered by physician users and guide decision-making regarding the benefit-risk profile of the TBE device in individual patients.

Table 37: Outcomes reported in TBE Pivotal Study that may be higher than corresponding reported rates for non-branched devices.

	Aneurysm Arm	**Non-Aneurysm Arm**			
	Aneurysm Cohort (n=84)	**Dissection Cohort (n=132)**	**Traumatic Transection Cohort (n=9)**	**Other Isolated Lesions Cohort (n=13)**	**Total (n=238)**
Events through 12-Months					
Stroke	7 (8.3%)	6 (4.6%)	0%	1 (7.7%)	14 (5.9%)
Disabling Stroke	4 (4.8%)	3 (2.3%)	-	1 (7.7%)	8 (3.4%)
WHO Stroke	7 (8.3%)	6 (4.6%)	-	1 (7.7%)	14 (5.9%)

	Aneurysm Arm	Non-Aneurysm Arm			
	Aneurysm Cohort (n=84)	**Dissection Cohort (n=132)**	**Traumatic Transection Cohort (n=9)**	**Other Isolated Lesions Cohort (n=13)**	**Total (n=238)**
Branch New Dissection	1 (1.2%)	6 (4.5%)	0%	0%	7 (2.9%)
open surgical repair	0%	0%	-	-	0%
untreated resulting death	0%	0%	-	-	0%
Distal Aorta New Dissection	5 (6.0%)	0%	0%	2 (15.4%)	7 (2.9%)
open surgical repair	0%	-	-	0%	0%
untreated resulting death	0%	-	-	1 (7.7%)	1 (0.4%)
Proximal Aorta New Dissection	1 (1.2%)	8 (6.1%)	0%	0%	9 (3.8%)
open surgical repair	1 (1.2%)	6 (4.5%)	-	-	7 (2.9%)
untreated resulting death	0%	1 (0.8%)	-	-	1 (0.4%)
Core Lab Type I/III Endoleak	8/82 (9.8%)	5/121 (4.1%)	0%	0%	13/225 (5.8%)
Type I	3/82 (3.7%)	3/121 (2.5%)	-	-	6/225 (2.7%)
Type III	5/82 (6.1%)	2/121 (1.6%)	-	-	7/225 (3.1%)
Reintervention	1 (1.2%)	0%	-	-	1/225 (0.4%)
Note: This table was manually created.					

Based on the clinical endpoint outcomes presented above, there is reasonable assurance of the safety and effectiveness of the GORE® TAG® Thoracic Branch Endoprosthesis Device for the proposed intended use, that being patients with descending thoracic lesions who are high risk for surgical debranching.

B. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The Aneurysm hypothesis-driven cohort was successful in meeting its performance goal for the composite safety and effectiveness primary endpoint. As a fully endovascular option to preserve flow to the LSA during a TEVAR procedure, the GORE® TAG® Thoracic Branch Endoprosthesis allows for isolation of descending thoracic aortic lesions while maintaining perfusion to the LSA in patients who are high risk for surgical revascularization.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. These risks include aortic rupture (0.8%; through 12 months), lesion related mortality (1.7%; through 12 months), disabling stroke (1.5%; through 30 days), permanent paraplegia (0.4%; through 30 days), permanent paraparesis (1.3%; through 30 days, note two events were later adjudicated to not meet the definition), new onset renal failure requiring dialysis (0%; through 30 days), and reintervention (2.9%; through 12 months). The rates of these events are similar to the rates reported in non-branched TEVAR devices. Given the rates of Stroke, New Dissection, and Type I/III endoleak, the benefit of the GORE® TAG® Thoracic Branch Endoprosthesis is limited to those subjects at high risk for LSA debranching procedures.

Additional factors to be considered in determining probable risks and benefits for the GORE® TAG® Thoracic Branch Endoprosthesis included:

- limitation on the number of Subjects in Traumatic Transection and Other Isolated Lesions cohorts; and

- absence of full 5- year patient follow-up data.

1. Patient Perspectives

This submission did not include specific information on patient perspectives, or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that, for the endovascular treatment of lesions of the descending thoracic aorta, where maintenance of flow into the left subclavian artery is required, the probable benefits of the GORE® TAG® Thoracic Branch Endoprosthesis outweigh the probable risks.

C. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the device when used in accordance with the indications for use.

The pre-clinical testing performed in accordance with applicable guidance documents and national and international standards confirmed that the GORE® TAG® Thoracic Branch Endoprosthesis met its performance and design specifications. The clinical study met the pre-specified performance goal for safety and effectiveness. Therefore, it is reasonable to conclude that the benefits of use of the device for the indicated population outweigh the risk of illness or injury when used as indicated in accordance with the Instructions for Use (IFU).

XIV. CDRH DECISION

CDRH issued an approval order on (DATE). The final conditions of approval cited in the approval order are described below.

1. *Clinical Update:* Gore has agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for the IDE and Post-Approval studies, respectively, a summary of the number of patients for whom data are available, with the rates of mortality (device-and lesion-related), stroke (mRS ≥ 2), paraplegia / paraparesis, aortic enlargement in the region encompassed by the initial lesion, aortic rupture, Type I/III endoleaks, new dissections, loss of device integrity, device migration, loss of aortic / aortic branch patency, and additional surgical or interventional procedure related to the device or procedure. Reasons for secondary interventions and conversion to open surgery as well as causes of lesion-related death and rupture are to be described. Additional relevant information from commercial experience within and outside the United States is also to be included. A summary of any explant analysis findings is to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

2. *Continued Follow-up of the IDE Study Subjects*: This study is a non-randomized, multicenter, prospective study that consists of continued follow-up of all available subjects from the IDE Pivotal Study and the continued access subjects. The study design includes the assessment of the GORE® TAG® Thoracic Branch Endoprosthesis in treating lesions of the thoracic aorta in Zone 2. A total of 244 subjects were enrolled and eligible for analysis in the study across the 4 cohorts (including six continued access subjects). The remaining subjects will be followed annually for 5 years. Clinical outcomes include Procedural Success (defined as Device Technical Success with the absence of serious adverse events at 30 days, including: death, disabling stroke, paraplegia, paraparesis, new onset renal failure requiring permanent dialysis, unanticipated reintervention related to the device or the procedure, new ischemia, distal device-related thromboembolic events requiring intervention, life threatening bleed, myocardial infarction, prolonged intubation, laryngeal or phrenic nerve injury, renal dysfunction or volume overload requiring ultrafiltration, severe heart failure or hypotension, aortic rupture or new dissection) and Treatment Success (defined as Device Technical Success, with absence of all of the following at all appropriate follow-up windows: lesion-related mortality, disabling stroke, paraplegia and paraparesis, protocol-defined reintervention, new ischemia, aortic rupture, loss of patency, fistula formation, loss of device integrity, device migration, new dissection, Type I/III endoleak, and aortic enlargement). These endpoints will be analyzed descriptively, and PAS reports submitted on a yearly basis.

3. *GORE® TAG® Thoracic Branch Endoprosthesis Post-Market Surveillance Study*: This is a non-randomized, multicenter registry collecting data from consecutively treated patients. The objective of the registry is to ensure that the clinical outcomes during the commercial use of the GORE® TAG® Thoracic Branch Endoprosthesis are as anticipated. This study will enroll a minimum of 250 subjects and a maximum of 350 subjects treated with the GORE® TAG® Thoracic Branch Endoprosthesis with at least 100 subjects evaluable at 5 years post-implantation, and additional follow-up provided for all patients enrolled to 10 years unless lost to follow-up or subject death . This study will enroll a minimum of 45 Acute Type B Dissection subjects, 20 Other Isolated Lesions (including PAU and IMH) subjects, and 25 Traumatic Transection subjects. This study will have a minimum of 20 new sites and a maximum of 40 sites that were involved in the IDE. Subject follow-up for this registry is per standard medical practice at each participating site through 10 years post-treatment. Core Lab imaging analysis will be performed for the first five years and site reported imaging analysis through the ten years of the study. The analysis will include clinical data required to assess safety and performance of the GORE® TAG® Thoracic Branch Endoprosthesis, including: patient and anatomical

characteristics, procedural characteristics and outcomes, short-to-mid-term outcomes through 5 years, and long term outcomes from 5 years – 10 years (as available). The data collection will include: device- and lesion-related mortality, all-cause mortality, stroke (mRS ≥ 2), paraplegia / paraparesis, aortic enlargement (>5mm) in the region encompassed by the initial lesion, aortic rupture, Type I/III endoleaks, new dissections, loss of device integrity, device migration, loss of aortic / aortic branch patency, and additional surgical or interventional procedure related to the device or procedure. Outcomes will be reported using descriptive statistics.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications,Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval t and Restrictions: See approval order.