SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: GORE® EXCLUDER® Conformable AAA Endoprosthesis

Device Procode: MIH

Applicant's Name and Address: W. L. Gore & Associates, Inc.
32360 N. North Valley Parkway
Phoenix, AZ 85085

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200030

Date of FDA Notice of Approval: December 22, 2020

II. INDICATIONS FOR USE

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below:

- Adequate iliac / femoral access
- Infrarenal aortic neck treatment diameter range of 16–32 mm and a minimum aortic neck length of 15 mm
- Proximal aortic neck angulation is ≤60˚
- Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm.

III. CONTRAINDICATIONS

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE® EXCLUDER® Conformable AAA Endoprosthesis labeling.

V. DEVICE DESCRIPTION

The GORE® EXCLUDER® Conformable AAA Endoprosthesis (EXCC Device) provides endovascular treatment of infrarenal abdominal aortic aneurysms (AAA). The EXCC Device design incorporates modifications to the current GORE EXCLUDER Trunk-Ipsilateral Leg components, Aortic Extender components, and their associated delivery systems. The EXCC Device consists of two modular components, which are the Trunk-Ipsilateral Leg Component (EXCC Trunk-Ipsi) and the Aortic Extender Component (EXCC AE) as shown in **Figure 1**. The EXCC Trunk-Ipsilateral Leg Component is designed to be used with commercially available GORE® EXCLUDER® Contralateral Leg Components and Iliac Extender Components, which provide additional extension and seal into the common iliac arteries (**Figure 2**).

Stent-graft

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is a multi-component system consisting of a Trunk-Ipsilateral Leg Endoprosthesis (**Figure 1** and **Figure 2**), a Contralateral Leg Endoprosthesis (**Figure 2**), an Aortic Extender Endoprosthesis for proximal extension (**Figure 1**), and an Iliac Extender Endoprosthesis for distal extension. The graft material for each component is expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) that is supported by nitinol (nickel titanium alloy) wire along its external surface. Nitinol anchors and an ePTFE / FEP sealing cuff are located at the leading (proximal) end of the trunk and a sealing cuff is located at the leading (proximal) end of the Aortic Extender. All components have gold radiopaque markers for visualization. An ePTFE / FEP sleeve is used to constrain the endoprostheses on the delivery catheter (**Figure 3**).

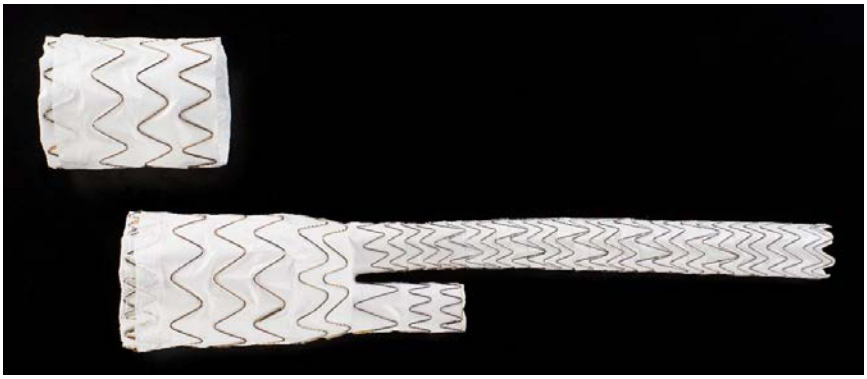

Figure 1. GORE® EXCLUDER® Conformable AAA Trunk-Ipsilateral Leg Endoprosthesis (Bottom) and Aortic Extender Endoprosthesis (Top)

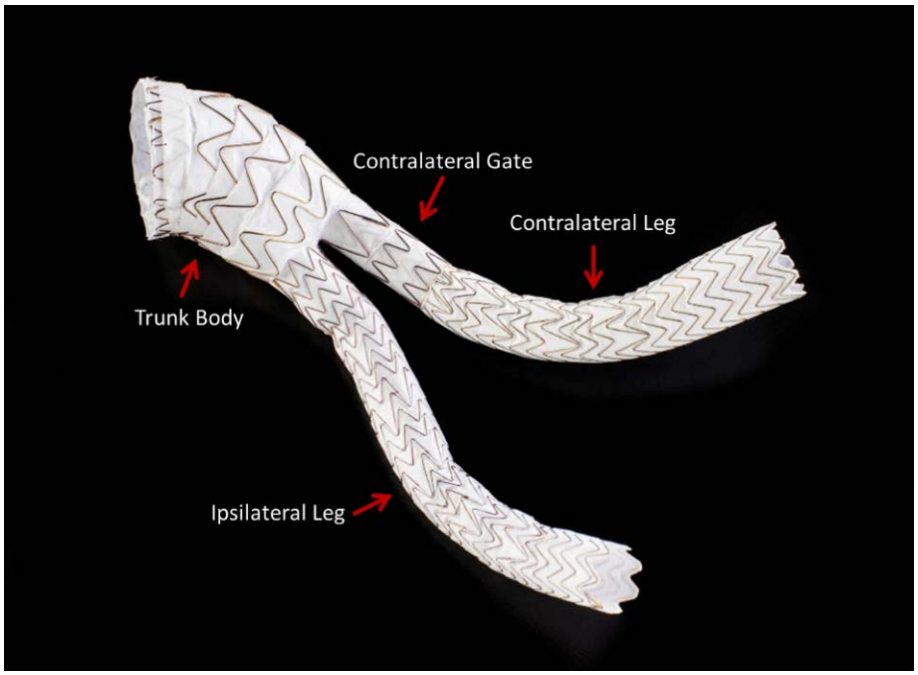

Figure 2. GORE® EXCLUDER® Conformable AAA Trunk-Ipsilateral Leg Endoprosthesis with GORE® EXCLUDER® Contralateral Leg Endoprosthesis within Contralateral Gate

Delivery System

The EXCC Trunk-Ipsilateral delivery system is similar to the currently marketed GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System in that it has a corresponding white handle with nested knobs for device deployment (**Figure 3**). The sewn sleeve incorporates the same sewn sleeve / deployment line mechanism as the GORE® C3® Delivery System. The EXCC Trunk-Ipsilateral delivery system includes the constraining/unconstraining mechanism for device repositioning, which is part of the currently available GORE® C3® Delivery System. In addition, the EXCC Trunk-Ipsi handle has an Angulation Control Knob to aide in angulating the device on catheter, which is an optional device feature (**Figure 3**). The catheter working length is 69 cm and the profiles are 15 Fr, 16 Fr and 18 Fr. Refer to the IFU for additional information.

Unique features to the EXCC delivery system are:

- Catheter angulation by rotating a gray knob on the delivery catheter handle for device positioning and deployment accuracy (optional feature)
- Secondary sleeve over the trunk body which constrains it to ~70% of its full diameter for improved device repositioning
- Longer and flexible leading tip to enhance trackability and deliverability in tortuous anatomy

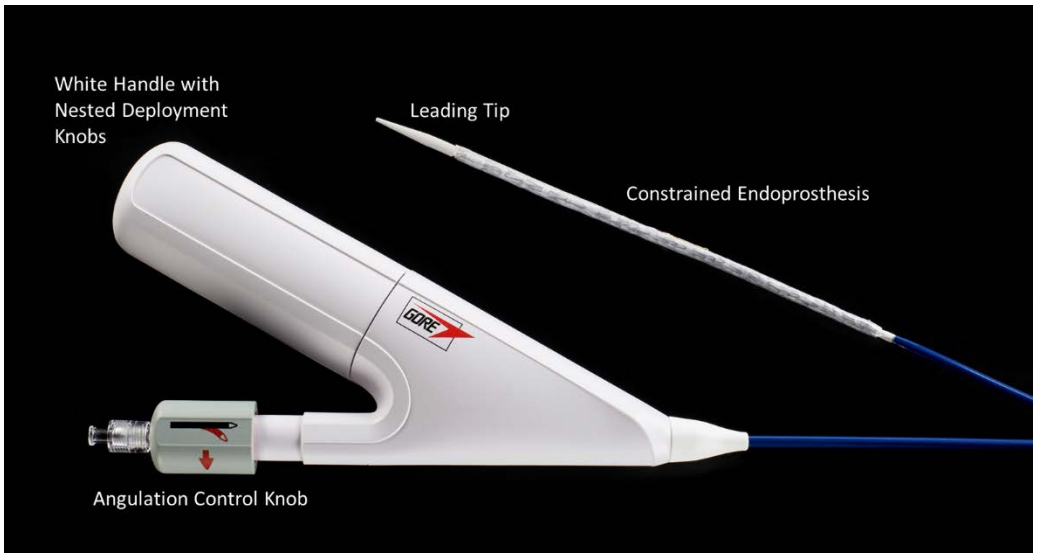

Figure 3. GORE® EXCLUDER® Conformable AAA Trunk-Ipsilateral Leg Endoprosthesis Delivery System Handle and Constrained Endoprosthesis on Delivery Catheter

Product Size Availability

Table 1 summarizes the device sizes and delivery system compatibility.

Table 1. GORE® EXCLUDER® Conformable AAA Endoprosthesis Trunk-Ipsilateral Leg and Aortic Extenders Sizing Summary

Part Number Trunk-Ipsilateral	Proximal Diameter	Overall Length	Ipsilateral Leg Diameter	Profile
CXT201212	20 mm	12 cm	12 mm	15 Fr
CXT201214	20 mm	14 cm	12 mm	15 Fr
CXT201216	20 mm	16 cm	12 mm	15 Fr
CXT201412	20 mm	12 cm	14.5 mm	15 Fr
CXT201414	20 mm	14 cm	14.5 mm	15 Fr
CXT201416	20 mm	16 cm	14.5 mm	15 Fr
CXT231212	23 mm	12 cm	12 mm	15 Fr
CXT231214	23 mm	14 cm	12 mm	15 Fr
CXT231216	23 mm	16 cm	12 mm	15 Fr
CXT231218	23 mm	18 cm	12 mm	15 Fr
CXT231220	23 mm	20 cm	12 mm	15 Fr
CXT231412	23 mm	12 cm	14.5 mm	15 Fr
CXT231414	23 mm	14 cm	14.5 mm	15 Fr
CXT231416	23 mm	16 cm	14.5 mm	15 Fr
CXT231418	23 mm	18 cm	14.5 mm	15 Fr
CXT231420	23 mm	20 cm	14.5 mm	15 Fr
CXT261212	26 mm	12 cm	12 mm	16 Fr
CXT261214	26 mm	14 cm	12 mm	16 Fr
CXT261216	26 mm	16 cm	12 mm	16 Fr
CXT261218	26 mm	18 cm	12 mm	16 Fr

Part Number Trunk-Ipsilateral	Proximal Diameter	Overall Length	Ipsilateral Leg Diameter	Profile
CXT261220	26 mm	20 cm	12 mm	16 Fr
CXT261412	26 mm	12 cm	14.5 mm	16 Fr
CXT261414	26 mm	14 cm	14.5 mm	16 Fr
CXT261416	26 mm	16 cm	14.5 mm	16 Fr
CXT261418	26 mm	18 cm	14.5 mm	16 Fr
CXT261420	26 mm	20 cm	14.5 mm	16 Fr
CXT281212	28.5 mm	12 cm	12 mm	16 Fr
CXT281214	28.5 mm	14 cm	12 mm	16 Fr
CXT281216	28.5 mm	16 cm	12 mm	16 Fr
CXT281218	28.5 mm	18 cm	12 mm	16 Fr
CXT281220	28.5 mm	20 cm	12 mm	16 Fr
CXT281412	28.5 mm	12 cm	14.5 mm	16 Fr
CXT281414	28.5 mm	14 cm	14.5 mm	16 Fr
CXT281416	28.5 mm	16 cm	14.5 mm	16 Fr
CXT281418	28.5 mm	18 cm	14.5 mm	16 Fr
CXT281420	28.5 mm	20 cm	14.5 mm	16 Fr
CXT321414	32 mm	14 cm	14.5 mm	18 Fr
CXT321416	32 mm	16 cm	14.5 mm	18 Fr
CXT321418	32 mm	18 cm	14.5 mm	18 Fr
CXT321420	32 mm	20 cm	14.5 mm	18 Fr
CXT361414	36 mm	14 cm	14.5 mm	18 Fr
CXT361416	36 mm	16 cm	14.5 mm	18 Fr
CXT361418	36 mm	18 cm	14.5 mm	18 Fr
CXT361420	36 mm	20 cm	14.5 mm	18 Fr

Aortic Extenders	Proximal Diameter	Overall Length	Ipsilateral Leg Diameter	Profile
CXA200005	20 mm	4.5 cm	N/A	15 Fr
CXA230005	23 mm	4.5 cm	N/A	15 Fr
CXA260005	26 mm	4.5 cm	N/A	15 Fr
CXA280005	28 mm	4.5 cm	N/A	16 Fr
CXA320005	32 mm	4.5 cm	N/A	18 Fr
CXA360005	36 mm	4.5 cm	N/A	18 Fr

A. Accessories and Other Required Devices

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is intended to be used with the following accessory devices for delivery or implantation:

- 0.035" (0.89 mm) 'super stiff' guidewire (or similar guidewire with a long floppy tip), 145 cm or longer
- Angiographic radiopaque marker catheter
- Contrast media
- Syringe
- Snare catheter
- Heparin and heparinized saline
- Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis

- 12 Fr, 14 Fr, 15 Fr, 16 Fr, or 18 Fr introducer sheaths (reference IFU for sizing)
- Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter IFU)
- Percutaneous transluminal angioplasty (PTA) balloons (reference IFU for sizing)

- Aortic Extender Endoprosthesis
  - 15 Fr, 16 Fr, or 18 Fr introducer sheath (reference IFU for sizing)
  - Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter IFU)
- Iliac Extender Endoprosthesis
  - 12 Fr, 14 Fr, and 15 Fr introducer sheaths (reference IFU for sizing)
  - PTA balloon catheters (reference IFU for sizing)

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of infrarenal abdominal aortic aneurysms including:

- Medical management
- Open surgical repair of the aneurysm
- Endovascular Aneurysm Repair (EVAR) using other endovascular devices

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

VII. MARKETING HISTORY

The EXCC device is currently approved for use in New Zealand and the European Union (EU), where the CE mark for the EU was obtained in March 2016. These countries include the following: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

The EXCC device has not been withdrawn from marketing for any reason.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Table 2 is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

Table 2. Potential Adverse Events

- allergic reaction and / or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials
- amputation
- anesthetic complications
- aneurysm enlargement
- aneurysm rupture and death
- arterial or venous thrombosis and / or pseudoaneurysm
- arteriovenous fistula
- bleeding, hematoma, or coagulopathy
- bowel complications (e.g., ileus, gastrointestinal bleeding, fistula, transient ischemia, infarction, necrosis)
- cardiac events (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
- claudication (e.g., buttock, lower limb)
- delivery catheter: damage, failure, difficulty / unable to remove
- death
- dissection, perforation, bleeding, or ruptures of the aortic vessel and surrounding vasculature
- edema
- embolization (micro and macro) with transient or permanent ischemia
- endoleak
- endoprosthesis or delivery system: improper component placement; incomplete component deployment; unintentional/premature component deployment; leading end catheter component retention; component migration; separation of graft material from stent; occlusion; infection; stent fracture; graft material failure, dilatation, erosion, puncture, perigraft flow
- fever and localized inflammation
- genitourinary complications (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- hemorrhage
- hepatic failure
- impotence
- infection (e.g., aneurysm, device or access sites)
- lymph fistula / complications
- multi-system organ failure
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
- occlusion / stenosis of device or native vessel
- post-implant syndrome
- pulmonary complications (e.g., pneumonia, respiratory failure)
- radiation injury, late malignancy
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- surgical cut down, bypass, or conversion
- tissue necrosis
- wound complications (e.g., infection, dehiscence)
- vascular spasm or vascular trauma (e.g., aorta dissection, aorta damage, ilio-femoral vessel dissection, bleeding, rupture, death)

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

IX. SUMMARY OF NONCLINICAL STUDIES

Nonclinical studies were completed to evaluate the EXCC device, 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 EXCC was developed based on the device risk assessment and is consistent with *FDA Non-Clinical Tests and Recommended Labeling of Intravascular Stents and Associated Delivery Systems*, April 18, 2010 and its addendum, *Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems*, August 30, 2013.

The relevant *in vitro* tests outlined in the guidance document and included in support of the GORE® EXCLUDER® Conformable AAA Endoprosthesis devices are summarized in **Table 3** below.

Table 3. Summary of In Vitro Test Results

Test	Test Summary	Results
Endovascular System		
Deployment accuracy	This test evaluates the ability of the EXCC components to be deployed at the intended vessel location in an anatomical model prior to constraining and re-positioning. **Acceptance Criteria:** The Trunk, must be within +/- 5 mm of desired target point and must be +/- 90° of desired orientation. The AE must be positioned within a maximum of + 5 mm anatomically proximal to the desired target point.	**PASS**

<table>
<tr><th>Test</th><th>Test Summary</th><th>Results</th></tr>
<tr><td>Stent Graft and Delivery Catheter Profile</td><td>This test evaluates the profile of the stent graft constrained on the delivery catheter.

Acceptance Criteria:
Device must meet the following profile requirement for each device type:
<table><tr><th>Stent-Graft</th><th>Profile (inches)</th></tr><tr><td>Trunk-Ipsilateral Leg
(20 and 23 mm diameters)</td><td>0.200</td></tr><tr><td>Trunk-Ipsilateral Leg
(26 and 28.5mm diameters)</td><td>0.213</td></tr><tr><td>Trunk-Ipsilateral Leg
(32 and 36 mm diameters)</td><td>0.239</td></tr><tr><td>Aortic Extender
(20mm – 26mm diameters)</td><td>0.200</td></tr><tr><td>Aortic Extender
(28.5mm – 32mm diameters)</td><td>0.213</td></tr><tr><td>Aortic Extender
(36mm diameter)</td><td>0.239</td></tr></table></td><td>PASS</td></tr>
<tr><td colspan="3">Endoprosthesis</td></tr>
<tr><td>Acute Migration</td><td>This test evaluates the migration resistance of the EXCC Device in an anatomical model with physiological pressure and flow at 37°C.

Acceptance Criteria:
Acutely measure migration (longitudinal displacement from the initial deployment location) distance in-vitro must be within ±1mm.</td><td>PASS</td></tr>
<tr><td>Durability Evaluation</td><td>This test evaluates durability through pulsatile fatigue testing.

Acceptance Criteria:
The EXCC Device must withstand the pulsatile test conditions for a simulated ten-year service life without stent fractures, separation of wire terminations, failure of the ePTFE, or ePTFE/Nitinol composite or other device damage that would compromise device function.</td><td>PASS</td></tr>
<tr><td>Active Fixation Durability</td><td>This test evaluates the durability of the stent anchors through simulated physiological loading conditions.

Acceptance Criteria:
The EXCC endoprosthesis must withstand the physiologic pulsatile loading for a simulated ten-years without anchor fractures and/or anchor load path damage that could compromise device function.</td><td>PASS</td></tr>
<tr><td>Integral Water Permeability</td><td>This test evaluates the water leak rate through the walls of the device at a constant pressure.

Acceptance Criteria:
Characterize the integral water permeability of the EXCC device and compare test results to the GORE® EXCLUDER® AAA Endoprosthesis historical range of 0.05 to 1.57 ml/min/cm2.</td><td>PASS</td></tr>
<tr><td>Radial compression</td><td>This test evaluates the force to compress the proximal end of the EXCC Device using a radial force tester at 37°C.

Acceptance Criteria:
Characterize the radial compression strength of the EXCC endoprostheses and demonstrate that performance is comparable or better to existing GORE® EXCLUDER® AAA Endoprosthesis Devices of similar sizes.</td><td>PASS</td></tr>
</table>

Test	Test Summary	Results
Sealing/Leak	This test evaluates the amount of water leakage and leak rate of the EXCC Device using simulated physiologic temperatures and mean arterial blood pressure. **Acceptance Criteria:** Characterize sealing and leakage of the EXCC Device and demonstrate that performance is comparable or better to the GORE® EXCLUDER® AAA Endoprosthesis Device data.	**PASS**
Compressed Stent Graft Length*	This test evaluates the length of the stent-graft mounted on the delivery catheter prior to deployment with a 0.035" guidewire or processing mandrel in place. **Acceptance Criteria:** All EXCC Devices must be within the compressed stent-graft length required ranges.	**PASS**
Post Deployment Stent Graft Diameter	This test evaluates proximal and distal diameter (OD) of a deployed EXCC stent graft in a 37°C water bath. **Acceptance Criteria:** The proximal and distal diameters of the EXCC must be within the required ranges.	**PASS**
Modular Component Separation Force	This test evaluates the peak pull out force and length of overlap while, in a heated chamber at 37°C, the stent graft system components are pulled apart longitudinally at a uniform rate. **Acceptance Criteria:** Characterize the modular component separation force of the EXCC device and demonstrate that performance is comparable or better to the GORE® EXCLUDER® AAA Endoprosthesis Device data.	**PASS**
Magnetic Resonance Imaging Safety	This test evaluates the magnetic resonance imaging (MRI) compatibility and characterizes the displacement/ torque, heating, and image distortion sensitivities. **Acceptance Criteria:** The EXCC Device must be labeled as MR Conditional at 1.5 and 3.0 Tesla.	**PASS**
Radiopacity	This test evaluates the visibility of the EXCC components under fluoroscopy. **Acceptance Criteria:** The loaded EXCC endoprosthesis, delivery catheters, and deployed devices must demonstrate sufficient radiopacity for safe and efficacious clinical use.	**PASS**
Bend Radius	This test evaluates the minimum radius of curvature that the EXCC Device can accommodate without kinking. Kinking is defined as discontinuity of curvature or a buckling of the wall. **Acceptance Criteria:** The bend radius must be less than or equal to 15.2 mm at the center body ring and the center of the ipsi leg.	**PASS**

<table>
<tr><th>Test</th><th>Test Summary</th><th>Results</th></tr>
<tr><td>Longitudinal Tensile Strength</td><td>This test evaluates the yield/ break point of the devices when pulled at a uniform strain rate.

Acceptance Criteria:
All devices must meet the minimum tensile strength value, as specified below.

<table>
<tr><th>Component</th><th>Size (mm)</th><th>Longitudinal Tensile Strength (kgf)</th></tr>
<tr><td rowspan="6">Trunk, Aortic Extender</td><td>20</td><td>x ≥ 9.32</td></tr>
<tr><td>23</td><td>x ≥ 12.25</td></tr>
<tr><td>26</td><td>x ≥ 15.44</td></tr>
<tr><td>28</td><td>x ≥ 19.18</td></tr>
<tr><td>32</td><td>x ≥ 23.85</td></tr>
<tr><td>36</td><td>x ≥ 28.86</td></tr>
<tr><td rowspan="2">Ipsilateral Leg</td><td>12</td><td>x ≥ 3.81</td></tr>
<tr><td>14</td><td>x ≥ 4.72</td></tr>
</table>
</td><td>PASS</td></tr>
<tr><td>Wall Thickness</td><td>This test evaluates the wall thickness.

Acceptance Criteria:
All samples must fall within the wall thickness range 0.031 mm ≥ x ≥ 0.103 mm.</td><td>PASS</td></tr>
<tr><td>Stent Graft Burst Pressure</td><td>This test evaluates the burst pressure of the device.

Acceptance Criteria:
All devices must meet or exceed minimum burst pressure requirement of 37 PSI.</td><td>PASS</td></tr>
<tr><td>Bacterial Endotoxins</td><td>This test evaluates the biological safety of the device and catheter components which make direct blood contact.

Acceptance Criteria:
Bacterial endotoxins of the EXCC Device and catheter components must not exceed the endotoxin limit of 20 EU/device, as established according to the guidance provided by ANSI/AAMI ST72.</td><td>PASS</td></tr>
<tr><td colspan="3">Delivery System</td></tr>
<tr><td>Catheter Bond and Leading Tip Tensile*</td><td>This test evaluates the tensile strengths of the catheter bonds and leading tip bond.

Acceptance Criteria:
The tensile strength of the catheter bonds and the bond strength of the leading tip attachment to the delivery catheter shaft must be ≥ 8.1 lbf.</td><td>PASS</td></tr>
<tr><td>Catheter Working Length*</td><td>This test evaluates the length of the catheter from the leading tip to the handle strain relief with a 0.035” guidewire or processing mandrel in place.

Acceptance Criteria:
The delivery catheter working length must be within the required range.</td><td>PASS</td></tr>
<tr><td>Guidewire Component Compatibility*</td><td>This test evaluates the compatibility of the EXCC delivery catheters with a 0.035” guidewire.

Acceptance Criteria:
The catheter must be compatible with a 0.035” guidewire. Insertion must be without obstruction or excessive force.</td><td>PASS</td></tr>
</table>

Test	Test Summary	Results
Introducer Sheath Compatibility*	This test evaluates the compatibility of the EXCC Device with an introducer sheath. **Acceptance Criteria:** The delivery catheter loaded with the crushed endoprosthesis must be able to successfully pass through the recommended sheath; the entire catheter must successfully exit the sheath.	**PASS**
Delivery System Deployment Force	This test evaluates the force required to deploy the EXCC Device in an appropriate model in a water bath at 37°C. **Acceptance Criteria:** The deployment force of each deployment line must be less than or equal to the current specification requirements of ≤ 5.0 lbf for primary sleeve deployment lines and ≤ 3.27 for secondary sleeve deployment line.	**PASS**
Deployment Reliability*	This test evaluates various aspects of deployment including flushable guidewire lumen, balloon compatibility, guidewire compatibility, sheath compatibility, pushability, trackability, torquability, sleeve containment and attachment, steering wire actuation, constraining loop actuation, deployment, and catheter retraction. **Acceptance Criteria:** The delivery catheter must be flushable, compatible with specified balloons, guidewires, and sheaths in simulated anatomy and provide sufficient ability to advance the device to the correct location. The endoprosthesis must fully deploy. All deployment lines, delivery catheters and sheaths must be fully removable without impacting the deployed device. Specified components must meet all relevant post-deployment dimensional and physical inspection requirements.	**PASS**
Catheter Angular Rotation to Failure	This test evaluates the number of EXCC catheter rotations to failure with the leaking end fixed in a tortuous model, in a 37°C water bath. **Acceptance Criteria:** With the tip restrained, the catheter must allow at least 360° of handle rotation without mechanical damage or failure.	**PASS**
Catheter Leak	This test evaluates the catheter's ability to prevent leakage from the guidewire lumen. **Acceptance Criteria:** Pressure at which leakage of the delivery catheter guidewire lumen occurs must be ≥ 1.5 atm for all devices.	**PASS**
Handle Sealing*	This test evaluates the leakage rate of the EXCC handle. **Acceptance Criteria:** At 100 mmHg, the handle must not leak at a rate higher than 2 ml/min.	**PASS**
Deployment Mechanism to Line Tensile Strength*	This test evaluates the tensile strength required of the catheter deployment knobs to lines. **Acceptance Criteria:** The deployment line attachment strength for the primary and secondary sleeve deployment lines must be greater than the deployment force.	**PASS**
Lock Mandrel, Constraining Loop and Steering Wire Attachment Force*	This test evaluates the tensile strength required of the lock mandrel, constraining loop and steering wire to the catheter deployment knobs. **Acceptance Criteria:** Attachment Strength of these components must be > 8.0 lbf.	**PASS**

*Testing was also completed to support the 36-month shelf-life study (See Section IX-D).

B. Animal Studies

The EXCC was subjected to one GLP animal study to evaluate the safety and performance of the device. The GLP *in vivo* animal study demonstrated the safety and overall product performance of the EXCC *in vivo* in a total of 4 domestic swine. **Table 4** summarizes the result of the GLP study conducted on finished, sterile devices.

Table 4. Summary Result of the GLP Animal Study

Study Description	Study Overview	Purpose	Summary of Test Results
#2288SC An Acute Evaluation of the GORE® EXCLUDER® Conformable AAA Endoprosthesis Trunk-Ipsilateral Leg Component and Aortic Extender Component in the Thoracic Aorta of Domestic Swine	- 4 domestic swine - Thoracic aorta - Acute study; animals euthanized following device deployment - Chronic study leveraged from Gore® Excluder® device	To evaluate the functionality and safety of the EXCC when implanted in the normal thoracic aorta of domestic swine.	Delivery System Functionality: 4 of 4 EXCC devices received passing scores for all functional performance attributes. Endoprosthesis Functionality: 4 of 4 EXCC devices received passing scores for all functional performance attributes. Thrombus on Delivery Catheter: 8 of 8 delivery catheters were free of thrombus formation following withdrawal. Aortic Damage: 4 of 4 animals did not have aortic damage.

C. Biocompatibility Studies

Biocompatibility testing was conducted on the EXCC in accordance with applicable Good Laboratory Practices (21 CFR §58) and ISO 10993-1: 2009, *Biological Evaluation of Medical Devices*. Tests were conducted separately on product manufactured, packaged and sterilized using materials and procedures intended for the marketed product for the delivery system and the stent.

The EXCC delivery system is classified as an externally-communicating device in limited contact (< 24 hrs) with circulating blood. The stent-graft is classified as an implant device in permanent contact (> 30 days) with blood.

All testing performed met the pre-specified acceptance criteria. A summary of the biocompatibility testing conducted can be found in **Table 5**.

Table 5. Summary of GORE® EXCLUDER® Conformable AAA Endoprosthesis Biocompatibility Testing

Test Performed	Test Description	Stent	Delivery System	Results
Cytotoxicity	L929 MEM Elution	X	X	Non-cytotoxic
Sensitization	Kligman Maximization	X	X	Non-sensitizing
Irritation / Intracutaneous Reactivity	Intracutaneous Injection Test in Rabbits	X	X	Non-irritating
Acute Systemic Toxicity	Acute Systemic Toxicity Study in Mice	X	X	Non-toxic
Pyrogenicity	Rabbit Pyrogen Study (Material-Mediated)	X	X	Non-pyrogenic
Implantation*	Muscle Implantation Study in Rabbits	X	N/A	Non-irritant
Hemocompatibility Hemolysis	Hemolysis-Rabbit Blood (Direct and Indirect Contact)	X	X	Non-hemolytic
Hemocompatibility Coagulation	Partial Thromboplastin Time Assay (Direct Contact)	X	X	No effect on coagulation
Hemocompatibility Complement	SC5b-9 Complement Activation Assay (Direct Contact)	X	X	Not a complement activator
Hemocompatibility Thrombogenicity	In vivo Thrombogenicity Direct Contact*	X	X	Non-thrombogenic
Subacute / Subchronic/ Chronic Toxicity	Chemical Characterization/ Toxicological Risk Evaluation	X	N/A	Non-toxic
Genotoxicity	Chemical Characterization/ Toxicological Risk Evaluation	X	N/A	Non-mutagenic Non-clastogenic
Carcinogenicity	Chemical Characterization/ Toxicological Risk Evaluation	X	N/A	No carcinogenic risks
Reproductive Developmental Toxicity	Chemical Characterization/ Toxicological Risk Evaluation	X	N/A	No reproductive or developmental toxicity risks

* Evaluated as part of the animal studies outlined in Section B, above.

D. Sterilization, Packaging, and Shelf-Life

The EXCC device 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 36 months has been established for the EXCC 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 4**.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study (AAA 13-03) to establish a reasonable assurance of safety and effectiveness of endovascular repair of infrarenal abdominal aortic

aneurysms with the GORE® EXCLUDER® Conformable AAA Endoprosthesis (EXCC device) in the US under IDE #G150057. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

The AAA 13-03 study was a prospective, multicenter, non-randomized clinical study with two parallel substudies, designed to evaluate the safety and effectiveness of the EXCC Device for the treatment of infrarenal AAA in patients with short and/or angulated aortic necks. The substudies are described as follows:

- Short Neck Substudy: Subjects with AAA having aortic neck angulation ≤ 60˚ and infrarenal aortic neck length ≥ 10 mm

- High Neck Angulation Substudy: Subjects with AAA having aortic neck angulation > 60˚ and ≤ 90˚ and infrarenal aortic neck length ≥ 10 mm

Data from the Short Neck Substudy were the basis for the PMA approval decision, and therefore, this SSED addresses the results of the Short Neck Substudy only. At the time of this publication, enrollment in the High Neck Angulation Substudy is underway and no data on the High Neck Angulation Substudy patients has been analyzed yet. The Short Neck Substudy will further be referred to as the "study" in this document.

A. Study Design

Patients were treated between December 19, 2017 and February 27, 2019. The database for this PMA reflected data collected through April 29, 2020 and included 80 patients. There were 31 investigational sites in the US. Patients were enrolled into the clinical study provided all inclusion and no exclusion criteria were met. Subjects were evaluated through hospital discharge and follow-up visits at one and six months, and annually through 5 years post treatment.

The study was a prospective, multi-center, non-randomized clinical study.

The primary safety endpoint was a composite of the following within 30 days of the initial procedure: death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, procedural blood loss > 1000 mL, and thromboembolic events (including limb occlusion and distal embolic events). A performance goal of 79% of freedom from procedural safety events was developed to evaluate safety using historical GORE® EXCLUDER® AAA Device (EXC) data.

The primary effectiveness endpoint was a composite of technical success (successful access and deployment of all required EXCC Device components) and freedom from the following within 12 months of the initial procedure: Type I endoleak, Type III endoleak, migration (10 mm or more), AAA enlargement ≥ 5 mm with or without intervention,

AAA rupture, and conversion to open repair. A performance goal of 80% was developed to evaluate device effectiveness using historical EXC data.

The analysis of the primary safety endpoint was intended to test the hypothesis that the safety of the EXCC Device exceeds the performance goal of 79% free from safety endpoint events. The analysis of the primary effectiveness endpoint was intended to test the hypothesis that the effectiveness of the EXCC Device exceeds the performance goal of 80% free from effectiveness endpoint events.

The hypotheses were specified as follows:

Safety hypothesis:

$H_0 : P_{SE} \leq 0.79$

$H_A : P_{SE} > 0.79$

Effectiveness hypothesis:

$H_0 : P_{EE} \leq 0.80$

$H_A : P_{EE} > 0.80$

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. The initial step in Gore's review included Gore Imaging Sciences (GIS) performing an angle assessment. Patients that passed the initial angle assessment were further evaluated by GIS to ensure that the anatomy, characterized by vessel diameters and sealing zone lengths, were within the intended use parameters of the EXCC Device. At the conclusion of the process, the site was notified by Gore on the patient's eligibility (Accept / Reject) and, for accepted patients, their substudy assignment.
- 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 AAA 13-03 Short Neck substudy was limited to patients who met the following inclusion criteria:

- AAA meeting any of the following criteria:
  - Maximum diameter ≥ 50 mm
  - Rapid growth (> 5 mm in a 6-month period)
  - Non-ruptured AAA presenting with clinical symptoms
- Adequate anatomy to receive the EXCC Device, including:
  - Adequate iliac / femoral access
  - Infrarenal aortic neck diameter 16-32 mm
  - Infrarenal aortic neck length ≥ 10 mm
  - Aortic neck angle ≤ 60˚
  - Distal iliac artery seal zone ≥ 10 mm
  - Iliac artery diameter 8-25 mm
- An Informed Consent Form (ICF) signed by subject
- Male or infertile female*
- Able to comply with Protocol requirements including following-up
- Life expectancy > 2 years
- Age ≥ 21 years

* Infertile female – condition which prevents pregnancy e.g., hysterectomy, tubal ligation or post-menopausal for greater than 1 year

Patients were not permitted to enroll in the AAA 13-03 Short Neck substudy if they met any of the following exclusion criteria:

- Mycotic or ruptured aneurysm
- Known concomitant thoracic aortic aneurysm which requires surgical intervention
- Renal insufficiency defined as creatinine > 2.5 mg / dL or patient undergoing dialysis
- New York Heart Association (NYHA) class IV
- Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s)
- Severely tortuous or stenotic iliac and / or femoral arteries
- Patient has body habitus or other medical condition which prevents adequate delineation of the aorta
- Participating in another investigational device or drug study within 1 year of treatment
- Systemic infection which may increase the risk of endovascular graft infection
- Known degenerative connective tissue disease, e.g., Marfan or Ehler-Danlos Syndrome
- Planned concomitant surgical procedure or major surgery within 30 days of treatment date
- Known history of drug abuse
- Known sensitivities or allergies to the device materials

2. Follow-up Schedule

All patients were required to return for follow-up examinations at 1, 6, 12, 24, 36, 48 and 60 months.

Pre-operatively, patients were required to have a physical examination, serum creatinine concentration test and contrast enhanced spiral computed tomography (CT).

Operatively, patients were required to have angiography performed at the conclusion of the procedure.

Post-operatively, patients were required to have a physical examination and contrast enhanced CT scan at each visit interval. At the one-month interval, a non-contrast CT was also required.

Adverse events and complications were recorded at all visits. The key timepoints are shown below in the tables summarizing safety and effectiveness.

Table 6 outlines the required screening evaluations and follow-up visit procedures for subjects.

Table 6. Schedule of Events

Diagnostic Test	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 computed tomography (contrast)	X			X	X	X
Spiral computed tomography (non-contrast)				X		
Angiography		X				

3. Clinical Endpoints

With regards to safety, the primary safety endpoint was a composite of the following within 30 days of the initial procedure, based on the definitions provided by Chaikof et al:

- Death
- Stroke
- Myocardial Infarction
- Bowel Ischemia
- Paraplegia
- Respiratory Failure
- Renal Failure
- Procedural Blood Loss > 1000 mL
- Thromboembolic Events (including limb occlusion and distal embolic events)

With regards to effectiveness, the primary effectiveness endpoint was defined as a composite of technical success (successful access and deployment of all required EXCC device components) and freedom from:

- Type I endoleak in the 12-month window
- Type III endoleak in the 12-month window
- Migration (10 mm or more) between the one month and at the 12-month window
- AAA enlargement ≥ 5 mm with or without intervention between the one-month and the 12-month window
- AAA rupture through the 12-month window
- Conversion to open repair through the 12-month window

With regard to overall study success, both the primary safety endpoint and primary effectiveness endpoint performance goals must be exceeded in order to achieve study success.

In addition to the primary effectiveness endpoints, a second group of effectiveness endpoints were assessed at each study follow-up interval and were reported descriptively and independent of the performance goals. The secondary effectiveness endpoints were defined as the following:

- Aneurysm-related mortality
- Stent fracture based on Core Lab analysis
- Individual elements of the primary safety and effectiveness endpoints
- Reintervention
- Type II endoleak
- Type IV endoleak
- Index Procedure Blood Loss
- Index Procedure Time
- Length of Hospital Stay (initial hospitalization)

B. Accountability of PMA Cohort

At the time of database lock, of 80 patients enrolled in the PMA study, 79 patients are available for analysis of the primary safety endpoint at 1 month and 66 were available for analysis of the primary effectiveness endpoint at 1 year.

Compliance with the study follow-up visits and imaging requirements for subjects implanted with the EXCC Device are summarized in **Table 7**. Ninety-nine (99) percent (79/80) of eligible subjects had a 1-month follow-up visit. Ninety-six (96) percent (77/80) eligible subjects had a 6-month follow up visit. Ninety-four (94) percent (75/80) eligible subjects had

a 12-month follow up visit. At the time of data export, no subjects were lost to follow-up or discontinued. There were six (6) subject deaths reported in the study.

Table 7. Subject Disposition and Compliance by Study Interval

		Follow-up Compliance[1]					Events Prior to Next Interval[1]			
Study Period	Eligible for Follow-Up	Subjects with Visit Window[2]	Physical Exam Performed	Any CT Scan Performed	Contrast CT Performed	Within Window No CT Yet[3]	Death	Conversion	Discontinued	Not Due for Next Window
Procedure	80	-	-	-	-	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	80	-	-	-	-	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 Month	80	79 (98.8%)	77 (96.3%)	79 (98.8%)	77 (96.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 Months	80	77 (96.3%)	72 (90.0%)	75 (93.8%)	71 (88.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 Months	80	75 (93.8%)	72 (90.0%)	74 (92.5%)	69 (86.3%)	0 (0%)	4 (5.0%)	0 (0%)	0 (0%)	3 (3.8%)
24 Months	73	13 (17.8%)	10 (13.7%)	13 (17.8%)	10 (13.7%)	58 (79.5%)	2 (2.7%)	0 (0%)	0 (0%)	71 (97.3%)

Study period definitions: Procedure (0-0 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).

1. Percentages are based on number of subjects eligible for follow-up in study period.
2. Any visit consisting of physical exam or CT scan.
3. Subjects still within the study window out of those who have not yet had a CT scan.

Table 8 summarizes the evaluated Core Lab parameters over prescribed follow-up time windows for subjects in the study. Core Lab evaluations of endoleaks, patency, AAA rupture, migration, wire fracture, extrusion, lumen obstructions, device compression, and diameter change were dependent on the availability of a contrast-enhanced CT scan. At 12-month follow-up, 74 subjects had a CT performed. Of those, 69 subjects had a contrast enhanced CT performed and five (5) subjects had only a non-contrast enhanced CT performed. Of the 74 CTs that were performed at the 12-month follow-up visit, the Core Lab was not able to evaluate all parameters for each CT that was submitted. At the 12 month follow-up visit interval the Core Lab was able to evaluate 67 subjects for endoleaks, 68 subjects for component patency, 69 subjects for AAA rupture, 73 subjects for migration, 71 subjects for extrusion/erosion, 68 subjects for lumen obstruction, 73 subjects for device compression and 73 subjects for diameter change.

Five (5) subjects had a non-contrast CT performed at the 12-month follow-up visit in lieu of a contrast enhanced CT due to reasons including decline in subject renal function or incorrect CT performed by site radiology department in error. Three (3) subjects did not have any CT performed due to reasons including CT cost or site's inability to contact the subject. Three (3) subjects did not have a 12-month CT performed due to subject death.

Table 8. Evaluability of Core Lab Parameters

Study Period	Eligible for Follow-up	Endoleak Evaluable (All Types)	Component Patency Evaluable	AAA Rupture Evaluable	Migration Evaluable	Wire Fracture Evaluable[1]	Extrusion /Erosion Evaluable	Lumen Obstruction Evaluable	Device Compression Evaluable	Diameter Change Evaluable[2]
1 Month	80	75(93.8%)	76(95.0%)	77(96.3%)	79(98.8%)	73(91.3%)	79(98.8%)	77(96.3%)	79(98.8%)	-
6 Months	80	70(87.5%)	72(90.0%)	72(90.0%)	75(93.8%)	69(86.3%)	75(93.8%)	72(90.0%)	75(93.8%)	74(92.5%)
12 Months	80	67(83.8%)	68(85.0%)	69(86.3%)	73(91.3%)	71(88.8%)	73(91.3%)	68(85.0%)	73(91.3%)	73(91.3%)
24 Months	73	10(13.7%)	10(13.7%)	10(13.7%)	11(15.1%)	11(15.1%)	11(15.1%)	10(13.7%)	11(15.1%)	11(15.1%)

Study period definitions: 1 Month (15-59 days), 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days)

1. Wire fracture was considered evaluable if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed.
2. Diameter change was considered evaluable if baseline (1 Month) and follow-up measurement were both available.

C. Study Population Demographics and Baseline Parameters

Demographics

A summary of subject demographics can be found in **Table 9**. The demographics of the study population are typical for an EVAR study performed in the US.The majority of subjects enrolled were male 88.8% and white 93.8%. Enrolled subjects had a mean age of 73.5 years and a mean BMI of 29.5.

Table 9. Subject Demographics Characteristics

	AAA 13-03
Number of Enrolled Subjects	80
Sex at Birth	
Male	71(88.8%)
Female	9(11.3%)
Ethnicity	
Not Hispanic or Latino	75(93.8%)
Hispanic or Latino	1(1.3%)
Unknown	4(5.0%)
Race	
White	75(93.8%)
Black	3(3.8%)
Asian	1(1.3%)
American Indian or Alaska Native	0
Hawaiian or Pacific Islander	0
Other	2(2.5%)
Age (yrs)	
n	80
Mean (Std Dev)	73.5(8.14)
Median	73.5
Range	(56.0,96.0)
Weight (kg)	
n	80
Mean (Std Dev)	89.5(17.82)
Median	87.5

	AAA 13-03
Range	(53.2,132.9)
Height (cm)	
n	80
Mean (Std Dev)	173.9(9.68)
Median	173.4
Range	(144.4,199.4)
BMI (kg/m^2)	
n	80
Mean (Std Dev)	29.5(5.05)
Median	28.5
Range	(21.6,46.1)

Subject Baseline Medical History

A summary of subject baseline medical history is provided in **Table 10**. The majority of subjects had a history of hypercholesterolemia (87.5%), hypertension (73.8%), and tobacco use (66.3%).

Table 10. Subject Medical History

	AAA 13-03
Number of Enrolled Subjects	80
Hypercholesterolemia	70(87.5%)
Hypertension	59(73.8%)
Tobacco Use	53(66.3%)
Cancer	24(30.0%)
Chronic Obstructive Pulmonary Disease	20(25.0%)
Diabetes Mellitus	17(21.3%)
Cardiac Arrhythmia	14(17.5%)
Myocardial Infarction	14(17.5%)
Peripheral Vascular Disease	12(15.0%)
Renal Insufficiency	11(13.8%)
Cerebrovascular disease	10(12.5%)
Congestive Heart Failure	9(11.3%)
Coronary Artery Bypass Graft	9(11.3%)
Other Concomitant Aneurysm	5(6.3%)
Paraplegia	3(3.8%)
Thromboembolic Event	3(3.8%)

Pre-Treatment Measurements

All subjects met anatomical criteria for inclusion based on Gore Imaging Sciences (GIS) and Site evaluations. A summary of the maximum aortic diameter measured by the site and Core Lab are provided in **Table 11**. The median maximum aortic diameter measured by the site was 54.0 mm. The median maximum aortic diameter measured by the Core Lab was 56.5 mm.

Table 11. Comparison of Pre-Treatment Measurements (Site and Core Lab Data)

	Site	Core Lab
Maximum Aortic Diameter (mm)		
n	80	80
Mean (Std Dev)	55.8(6.07)	57.7(7.95)
Median	54.0	56.5
Range	(43.0,78.0)	(42.5,82.7)
Length from lowest renal artery to aortic bifurcation (mm)		
n	80	80
Mean (Std Dev)	115.9 (15.1)	127.1 (17.1)
Median	115.0	126.3
Range	(69.0, 160.0)	(97.0, 206.7)

A summary of site and GIS-reported pre-treatment measurements is provided in **Table 12**. The median infrarenal aortic neck angle measured by the site was 38.5˚ and the median proximal aortic neck length was 24.5 mm. The median infrarenal aortic neck angle measured by GIS was 38.0˚ and the median proximal aortic neck length was 21.7 mm.

Table 12. Comparison of Pre-Treatment Measurements (Site and GIS Data)

	Site	GIS
Proximal Aortic Neck Length (mm)		
n	80	80
Mean (Std Dev)	26.1(13.01)	23.9(13.07)
Median	24.5	21.7
Range	(10.0,90.0)	(10.0,95.0)
n < 15mm	6	23
Infrarenal Proximal Aortic Neck Angle (degrees)		
n	80	80
Mean (Std Dev)	36.6(20.41)	35.7(14.55)
Median	38.5	38.0
Range	(0.0,90.0)	(3.0,59.0)

A summary of site-reported pre-treatment measurements is provided in **Table 13**.

Table 13. Summary of Pre-Treatment Measurements (Site Data Only)

	AAA 13-03
Number of Enrolled Subjects	80
Aortic diameter at proximal implantation site (mm)	
n	80
Mean (Std Dev)	21.5 (2.7)
Median	21.1
Range	(16.0, 29.0)
Aortic diameter - 10 mm distal to proximal implantation site (mm)	
n	80
Mean (Std Dev)	21.8 (2.9)
Median	21.7
Range	(16.0, 29.4)
Native aortic bifurcation diameter (mm)	
n	80
Mean (Std Dev)	23.5 (4.8)
Median	23.0
Range	(15.5, 42.0)
Left common iliac diameter (mm)	
n	80
Mean (Std Dev)	13.2 (3.2)
Median	12.3
Range	(8.4, 25.0)
Right common iliac diameter (mm)	
n	80
Mean (Std Dev)	13.2 (2.8)
Median	12.6
Range	(8.0, 19.0)
Left access vessel diameter (mm)	
n	80
Mean (Std Dev)	9.0 (1.6)
Median	9.0
Range	(6.0, 12.7)
Right access vessel diameter (mm)	
n	80
Mean (Std Dev)	9.0 (1.7)
Median	9.0
Range	(6.0, 15.7)

* As a note, one subject had a site-reported pre-treatment infrarenal aortic neck angle of 90˚; however, that subject was enrolled into the study due to having a Gore measured infrarenal aortic neck angle of 52˚.

A summary of Core Lab-reported pre-treatment measurements is provided in **Table 14**.

Table 14. Summary of Pre-Treatment Measurements (Core Lab Data Only)

	AAA 13-03
Number of Enrolled Subjects	80
Length from lowest renal artery to left internal / external bifurcation (mm)	
n	80
Mean (Std Dev)	191.8 (20.7)
Median	190.4
Range	(147.4, 247.1)
Length from lowest renal artery to right internal / external bifurcation (mm)	
n	80
Mean (Std Dev)	191.9 (20.4)
Median	188.1
Range	(153.9, 244.9)

Device Usage

Table 15 describes device usage for subjects enrolled in the study. All subjects enrolled had a EXCC device implanted. A median of 2.0 devices per subject were implanted. Six (6) subjects had a EXCC Aortic Extender (EXCC AE) implanted. Three (3) subjects had an additional device implanted in the treated area or was connected to the study device components. Additional devices implanted included an external iliac artery stent and renal artery stent grafts. A listing of EXCC Trunk device sizes used in the study are found in **Table 16**. A listing of EXCC AE device sizes used in the study are found in **Table 17**.

Table 15. Summary of Device Usage Data at Initial Treatment

	AAA 13-03
Number of Subjects Enrolled	80
Number of Subjects with Devices Implanted at Initial Treatment	80
EXCLUDER Device Components	
Subjects with Trunks Implanted	80(100.0%)
Subjects with Contralateral Legs Implanted	79(98.8%)
Subjects with Aortic Extenders Implanted	6(7.5%)
Subjects with Iliac Extenders Implanted	8(10.0%)
Number of Devices Implanted	
2	41(51.3%)
3	37(46.3%)
4	2(2.5%)
Number of Devices Per Subject	
n devices	201
Mean (Std Dev)	2.5(0.6)
Median	2.0
Range	(2,4)
Subjects with Additional Devices Implanted at Procedure[1]	3(3.8%)
External iliac artery stent	1(1.3%)
Renal artery stent graft	2(2.5%)

[1] Additional devices in the treated area or connected to study device components.

Table 16. Distribution of Dimensions of EXCLUDER Trunks – Ipsilateral Legs Implanted at Initial Procedure

Proximal Diameter (mm)	Distal Diameter (mm)	Length (cm)	Devices (N=80)
20	12	12	-
20	12	14	-
20	12	16	-
20	14.5	14	2(2.5%)
20	14.5	16	1(1.3%)
23	12	12	-
23	12	14	1(1.3%)
23	12	16	3(3.8%)
23	12	18	2(2.5%)
23	14.5	12	3(3.8%)
23	14.5	14	1(1.3%)
23	14.5	16	10(12.5%)
23	14.5	18	5(6.3%)
26	12	12	1(1.3%)
26	12	14	-
26	12	16	2(2.5%)
26	12	18	2(2.5%)
26	14.5	12	4(5.0%)
26	14.5	14	6(7.5%)
26	14.5	16	10(12.5%)
26	14.5	18	7(8.8%)
28.5	12	12	-
28.5	12	14	-
28.5	12	16	2(2.5%)
28.5	12	18	1(1.3%)
28.5	14.5	12	6(7.5%)
28.5	14.5	14	3(3.8%)
28.5	14.5	16	2(2.5%)
28.5	14.5	18	1(1.3%)
32	14.5	14	3(3.8%)
32	14.5	16	1(1.3%)
32	14.5	18	-
36	14.5	14	-
36	14.5	16	1(1.3%)
36	14.5	18	-

Table 17. Distribution of Dimensions of EXCLUDER Aortic Extenders Implanted at Initial Procedure

Diameter (mm)	Length (cm)	Devices (N=6)
20	4.5	-
23	4.5	2(33.3%)
26	4.5	1(16.7%)
28.5	4.5	3(50.0%)
32	4.5	-
36	4.5	-

Procedure Characteristics

A summary of the index endovascular procedures is provided in **Table 18**. Median procedure times were 84.0 minutes. The majority of subjects in the study had percutaneous access on the left side (87.5%) and right side (90%). The median blood loss was 50.0 mL. One subject experienced blood loss of 1000 mL and subsequently had a blood transfusion with a blood volume of 600 mL replaced during the index procedure. During the index procedure, seven subjects had additional procedures as listed below.

- Coil embolization to treat right accessory renal artery
- Bare metal self-expanding stent to treat occlusive disease at the left iliac bifurcation.
- Balloon expanding stent to treat left renal artery
- Balloon expanding stent to treat right renal artery
- Femoral patch/endarterectomy to treat dissection from closure device injury
- Self-expanding stent to treat left external iliac occlusive disease
- Balloon expanding stent to treat left femoral artery puncture site for closure device failure

Table 18. Procedure Characteristics

	AAA 13-03
Subjects Initiating Procedure	80
Endovascular Access Method on Left Side	
Percutaneous	70(87.5%)
Cut-down	10(12.5%)
Cut-down and Conduit	0(0.0%)
Endovascular Access Method on Right Side	
Percutaneous	72(90.0%)
Cut-down	8(10.0%)
Cut-down and Conduit	0(0.0%)
Anesthesia Method[1]	
General	72(90.0%)
Regional	4(5.0%)
Local	3(3.8%)

	AAA 13-03
Procedure Time (minutes)	
n	80
Mean (Std Dev)	89.1(37.9)
Median	84.0
Range	(33,251)
Blood Loss (mL)	
n	80
Mean (Std Dev)	75.6(121.7)
Median	50.0
Range	(0,1000)
Total Fluoro Time (minutes)	
n	79
Mean (Std Dev)	16.4(7.4)
Median	14.0
Range	(8,42)
Contrast Used During Procedure (mL)	
n	79
Mean (Std Dev)	82.2(32.7)
Median	75.0
Range	(14,200)
Transfusion	1(1.3%)
Procedure Survival	80(100.0%)
Open Surgical Conversion	0(0.0%)
Additional Procedures at Treatment	7(8.8%)
PTA	0(0.0%)
Stent	5(6.3%)
Thrombectomy	0(0.0%)
Embolization	1(1.3%)
Endostaples	0(0.0%)
Other	1(1.3%)

[1] One subject's anesthesia method was monitored anesthesia care (MAC), which is not accounted for in the table.

Procedure Outcomes

A summary of procedure outcomes is provided in **Table 19**. The median hospital stay was 1.0 day.

Table 19. Procedure Outcomes

	AAA 13-03
Subjects Initiating Procedure	80
ICU Stay	9(11.3%)
ICU Duration (hours)	
n	17
Mean (Std Dev)	14.1(15.3)
Median	19.0
Range	(0,51)

	AAA 13-03
Hospital Survival	80(100.0%)
Hospitalization Duration (days)	
n	80
Mean (Std Dev)	1.2(0.6)
Median	1.0
Range	(1,4)

Table 20 describes the summary of technical success results. All enrolled subjects had procedural technical success.

Table 20. Summary of Technical Success Results

	AAA 13-03
Number of Enrolled Subjects	80
Technical Success	80(100.0%)
Femoral artery access obtained	80(100.0%)
EXCC Device successfully deployed within the proximal neck seal zone	80(100.0%)
Delivery catheters successfully removed	80(100.0%)
EXCC Device patent and free from significant twist, kinks, or obstruction (> 30% luminal stenosis) upon final deployment	80(100.0%)
Absence of type I or type III endoleak on completion angiography	80(100.0%)
Access site closure successful (either surgical or percutaneous)	80(100.0%)

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the single-arm cohort of 79 subjects available for the 30 day evaluation. The key safety outcomes for this study are presented below in **Table 21**. Adverse effects are reported in **Table 22** and **Table 23**. A summary of the causes of death is provided in **Table 24**.

The primary safety endpoint was a composite of the following within 30 days of the initial procedure: death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, procedural blood loss > 1000 mL, and thromboembolic events including limb occlusion and distal embolic events. The primary safety endpoint was analyzed for eligible subjects. Of the 80 enrolled subjects, 79 subjects completed the required assessments to be evaluated for the primary safety endpoint. The percentage of subjects free from a primary safety endpoint event was 100.0%. The lower confidence limit for freedom from primary safety endpoint events was 96.3%, which exceeded the performance goal of 79%. The results of the primary safety endpoint analysis are provided in **Table 21**.

Table 21. Primary Safety Endpoint Result

	AAA 13-03	95% LCL
Subjects Eligible for Primary Safety Endpoint Analysis	79	
Freedom from Primary Safety Endpoint Event	79/79(100.0%)	96.3%
Freedom from Death	79/79(100.0%)	
Freedom from Stroke	79/79(100.0%)	
Freedom from Myocardial Infarction	79/79(100.0%)	
Freedom from Bowel Ischemia	79/79(100.0%)	
Freedom from Paraplegia	79/79(100.0%)	
Freedom from Respiratory Failure	79/79(100.0%)	
Freedom from Renal Failure	79/79(100.0%)	
Freedom from Procedural Blood Loss >1000 mL	79/79(100.0%)	
Freedom from Thromboembolic Events	79/79(100.0%)	

95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method

Worst Case Sensivity Analysis

There was one (1) subject ineligible for Primary Safety analysis. In the worst case sensitivity analysis for the safety outcome, this subject was considered to have experienced an endpoint event. The resulting ratio was 79/80 subjects with freedom from a primary safety endpoint event, and the corresponding 95% lower confidence limit was 94.2% which exceeded the performance goal of 79%.

Adverse effects that occurred in the PMA clinical study:

Adverse events were defined as any untoward medical occurrence (that the investigator feels is a reportable event) experienced by a subject whether device related or not.

Adverse Device Effect were defined as any adverse event related to the use of an investigational medical device.

Serious Adverse Events (SAE) were defined as any event that:

- led to death
- led to serious deterioration in the health of a subject that:
- resulted in a life threatening illness or injury
- resulted in a permanent impairment of a body structure or a body function
- required inpatient hospitalization or prolongation of existing hospitalization
- resulted in medical or surgical intervention to prevent permanent impairment to a body structure or a body function.
- led to fetal distress, fetal death or a congenital abnormality or birth defect.

Major Adverse Events (MAE) were defined as any adverse event meeting a primary safety endpoint definition extended through 1 year. A summary of MAEs is found in

Table 22. Three (3) subjects died in the 12 month interval. One (1) subject's cause of death was pneumonia, which also met the definition for respiratory failure.

Table 22. Summary of Major Adverse Events

	Follow-Up Period				
	Procedure	**1 Month**	**6 Months**	**12 Months**	**Total**
Number of Enrolled Subjects	80	80	80	79	80
Any Major Adverse Event	0(0%)	0(0%)	0(0%)	3(3.8%)	3(3.8%)
Death	0(0%)	0(0%)	0(0%)	3(3.8%)	3(3.8%)
Stroke	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Myocardial Infarction	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Bowel Ischemia	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Paraplegia	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Respiratory Failure	0(0%)	0(0%)	0(0%)	1(1.3%)	1(1.3%)
Renal Failure	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Procedural Blood Loss >1000 ml	0(0%)	-	-	-	0(0%)
Thromboembolic Event	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval.
Study period definitions: Procedure (0 days), 1 Month (1-30 days), 6 Months (31-183 days), 12 Months (184-365 days), Total (0-365 days).
MedDRA Version: 23.0

A summary of procedure-related SAEs in the study is found in **Table 23**. At the time of data export, there were three site reported procedure-related SAEs in the study. One subject experienced an "incision site ecchymosis" on Post-operative Day (POD) 3, which resolved without treatment and sequelae on POD 14. Another subject experienced a right femoral artery pseudoaneurysm during the index procedure which was treated with surgical repair during the index procedure, and resolved without sequela on the same day. A third subject experienced a Type II endoleak on POD 749 which was treated with glue embolization; the endoleak remains ongoing.

There are no device-related SAEs in the study.

Table 23. Procedure-Related SAEs by Study Period

	Post-Treatment Follow-up Period						
	Procedure	**1 Month**	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**Total**
Number of Subjects	80	80	80	79	61	7	80
Any Serious Adverse Event	1 (1.3%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (14.3%)	3 (3.8%)
General disorders and administration site conditions	0 (0%)	0 (0%)	-	-	-	1 (14.3%)	1 (1.3%)
Vascular complications associated with device	-	-	-	-	-	1 (14.3%)	1 (1.3%)
Stent-graft endoleak	-	-	-	-	-	1 (14.3%)	1 (1.3%)
Injury, poisoning and procedural complications	1 (1.3%)	1 (1.3%)	-	-	-	0 (0%)	2 (2.5%)
Cardiac and vascular procedural complications	1 (1.3%)	0 (0%)	-	-	-	-	1 (1.3%)
Vascular pseudoaneurysm	1 (1.3%)	-	-	-	-	-	1 (1.3%)
Non-site specific procedural complications	0 (0%)	1 (1.3%)	-	-	-	-	1 (1.3%)
Incision site haemorrhage	-	1 (1.3%)	-	-	-	-	1 (1.3%)

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Entries Represent MedDRA SOC, HLT and PT and are identified by increasing level of indentation. Dashes are used below headings with zero values.
Study period definitions: Procedure (0 days), 1 Month (1-30 days), 6 Months (31-183 days), 12 Months (184-365 days), 24 Months (366-731 days), 36 Months (732-1096 days), Total (0-1096 days)
MedDRA Version: 23.0

There have been 6 subject deaths in the study. The survival estimate was 96.2% at one year. Freedom from aneurysm related mortality was 100%.

Table 24. Listing of Deaths

Study Day	Cause of Death (Lowest Level Term)
269	Ascites
270	Pneumonia
315	Cardiomyopathy
500	Septic shock
548	Sepsis
568	Cardiopulmonary failure

Unanticipated Adverse Device Effects (UADEs)

There have been no observed UADEs reported for subjects enrolled in this study.

2. Effectiveness Results

The analysis of primary effectiveness was based on the 66 evaluable patients at the 12 month time point. Key primary effectiveness outcomes are presented in **Table 25**.

The formal effectiveness assessment for the study was based on the primary endpoint of treatment success. This was defined as a composite of technical success (successful access and deployment of all required EXCC device components) and freedom from:

- Type I endoleak in the 12-month window

- Type III endoleak in the 12-month window
- Migration (10 mm or more) between the one-month and at the 12-month window
- AAA enlargement ≥ 5 mm with or without intervention between the one-month and the 12-month window
- AAA rupture through the 12-month window
- Conversion to open repair through the 12-month window

The primary effectiveness endpoint was analyzed for eligible subjects. Of the 80 enrolled subjects, 66 subjects were eligible for primary effectiveness endpoint analysis. The percentage of subjects free from a primary effectiveness endpoint event was 98.5%. The lower confidence limit for freedom from primary effectiveness endpoint event was 93.0%, which exceeded the primary effectiveness endpoint performance goal of 80%. The results of the primary effectiveness endpoint analysis are provided in **Table 25**.

Table 25. Primary Effectiveness Endpoint Results

	AAA 13-03	95% LCL
Subjects Eligible for Primary Effectiveness Endpoint Analysis	66	
Primary Effectiveness Endpoint Success	65(98.5%)	93.0%
Technical Success	66(100.0%)	
Successful Access	66(100.0%)	
Successful Deployment of Devices in the Intended Location	66(100.0%)	
Patent Device Components	66(100.0%)	
Absence of Type I and Type III Endoleak	66(100.0%)	
Successful Access Closure	66(100.0%)	
Freedom from Type I Endoleak in the 12-Month Window	66(100.0%)	
Freedom from Type III Endoleak in the 12-Month Window	66(100.0%)	
Freedom from Migration ≥ 10 mm between 1-Month and 12-Month Window	66(100.0%)	
Freedom from AAA Enlargement ≥ 5 mm	65(98.5%)	
Freedom from AAA Rupture	66(100.0%)	
Freedom from Conversion to Open Repair	66(100.0%)	

95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method

Worst Case Sensitivity Analysis

Fourteen (14) subjects were not eligible for primary effectiveness endpoint analysis due to missed follow-up or discontinuation. In the worst case sensitivity analysis, these subjects were considered to have experienced an endpoint event resulting in an overall success rate of 65/80 subjects (81.3%). The 95% lower confidence limit was 72.6% which did not exceed the performance goal, thus necessitating a tipping point analysis.

Tipping Point Analysis

Of the fourteen (14) subjects ineligible for analysis, three of those subjects did not have a contrast enhanced CT performed at their 1-month follow-up visit, eight subjects did not have a contrast enhanced CT at their 12-month follow-up visit (five of those subjects

received non-contrast CT scans in lieu of a contrast enhanced CT) and three subjects died in the 12-month analysis window. The primary effectiveness performance goal of 80% would tolerate a maximum of 8/14 subjects with endpoint events among the group of subjects who were ineligible for effectiveness analysis; whereas, the observed freedom from effectiveness endpoint events in the primary analysis was 65/66 (98.5%). In consideration of the observed rate of primary effectiveness events of 1/66 (1.5%), it is unlikely the tipping point threshold of 8/14 (57.1%) was reached among the subjects not evaluated.

Secondary Effectiveness Endpoint Results

In addition to the primary effectiveness endpoints, a second group of effectiveness endpoints was assessed for the study at each study follow-up interval. The endpoints were reported descriptively and independent of the performance goals. The secondary effectiveness endpoints were defined as the following:

- Aneurysm-related mortality
- Stent fracture based on Core Lab analysis
- Individual elements of the primary safety and effectiveness endpoints
- Reintervention
- Type II endoleak
- Type IV endoleak
- Index Procedure Blood Loss
- Index Procedure Time
- Length of Hospital Stay (initial hospitalization)
- The results of the secondary endpoint results by study period are provided in **Table 26**.

Table 26. Secondary Endpoint Results by Study Period

	Post-Treatment Follow-up Period						
	Procedure	**Post-Procedure**	**1 Month**	**6 Months**	**12 Months**	**24 Months**	**Total**
Number of Subjects	80	80	80	79	79	19	80
Number of Subjects with CT Scan	-	-	79	75	74	13	80
Aneurysm Related Mortality[1]	0/80	0/80	0/80	0/79	0/79	-	-
Stent Fracture[2,3]	-	-	0/73	0/69	0/71	0/11	0/80
Reintervention[1]	-	0/80	1/80(1.3%)	1/79(1.3%)	1/79(1.3%)	-	-
Type II Endoleak[2]	-	-	31/75 (41.3%)	24/70 (34.3%)	18/67 (26.9%)	4/10 (40.0%)	34/78 (43.6%)
Type IV Endoleak[2]	-	-	0/75	0/70	0/67	0/10	0/78
Indeterminate Endoleak[2]	-	-	3/75(4.0%)	1/70(1.4%)	3/67(4.5%)	0/10	6/78(7.7%)
Primary Effectiveness Endpoints Individual Elements[4]							
Freedom from Type I Endoleak[2]	-	-	75/75 (100.0%)	70/70 (100.0%)	67/67 (100.0%)	10/10 (100.0%)	78/78 (100.0%)
Freedom from Type III Endoleak[2]	-	-	75/75 (100.0%)	70/70 (100.0%)	67/67 (100.0%)	10/10 (100.0%)	78/78 (100.0%)
Freedom from Migration ≥10mm[2]	-	-	79/79 (100.0%)	75/75 (100.0%)	73/73 (100.0%)	11/11 (100.0%)	80/80 (100.0%)
Freedom from AAA Enlargement ≥5mm[2]	-	-	-	73/74 (98.6%)	72/73 (98.6%)	10/11 (90.9%)	75/77 (97.4%)
Freedom from AAA Rupture[1,2]	80/80 (100.0%)	80/80 (100.0%)	80/80 (100.0%)	79/79 (100.0%)	79/79 (100.0%)	19/19 (100.0%)	80/80 (100.0%)
Freedom from Conversion to Open Repair[1]	80/80 (100.0%)	80/80 (100.0%)	80/80 (100.0%)	79/79 (100.0%)	79/79 (100.0%)	19/19 (100.0%)	80/80 (100.0%)

Denominators used in calculation of percentages are number of subjects with an evaluable result. The total column presents rates through all follow-up.
Totals not included for aneurysm related mortality and re-intervention as both endpoints are derived from CEC-adjudicated data through the 12-month visit interval only.
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), Total (0-911 days)
1. CEC adjudicated site reported events.
2. Core Lab reported events.
3. Wire fracture was considered assessed and included in denominator if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed. All subjects were evaluated for wire fracture in at least one follow-up period.
4. Freedom from event in window, not cumulative.

Summary of Core Lab results

Table 27 summarizes all Core Lab device findings for subjects enrolled in the study. There have been no Core Lab-reported Type I, Type III, or Type IV endoleaks. In addition, there have been no Core Lab-reported non-patent device components, AAA rupture, migration, wire fracture, extrusion / erosion, lumen obstruction, and device compression. Thirty-three (33) subjects have had a Core Lab-reported Type II endoleak, and six (6) subjects have had an indeterminate endoleak reported. In the 12 month

follow-up visit window, there were 17 Core Lab-reported Type II endoleaks and three (3) indeterminate endoleaks.

Table 27. Summary of Core Lab Device Findings by Follow-up Period

	Post Treatment Follow-up Period				
	1 Month	**6 Months**	**12 Months**	**24 Months**	**Total**
Number of Subjects	80	79	79	19	80
Number of Subjects With CT Scan	79	75	74	13	80
Endoleak	33/75(44.0%)	25/70(35.7%)	21/67(31.3%)	4/10(40.0%)	36/78(46.2%)
Type I	0/75	0/70	0/67	0/10	0/78
Type IA	0/75	0/70	0/67	0/10	0/78
Type IB	0/75	0/70	0/67	0/10	0/78
Type II	31/75(41.3%)	24/70(34.3%)	18/67(26.9%)	4/10(40.0%)	34/78(43.6%)
Type III	0/75	0/70	0/67	0/10	0/78
Type IV	0/75	0/70	0/67	0/10	0/78
Indeterminate	3/75(4.0%)	1/70(1.4%)	3/67(4.5%)	0/10	6/78(7.7%)
Non-patent Component	0/35	0/33	0/30	0/4	0/37
Non-patent Trunk-Ipsilateral Leg	0/77	0/72	0/68	0/10	0/80
Non-patent Contralateral Leg	0/77	0/72	0/68	0/10	0/80
Non-patent Iliac Extender	0/35	0/33	0/30	0/4	0/37
AAA Rupture	0/77	0/72	0/69	0/10	0/80
Migration	0/79	0/75	0/73	0/11	0/80
Prosthesis Migration >=10mm	0/79	0/75	0/73	0/11	0/80
Intercomponent Migration >=10mm	0/79	0/75	0/73	0/11	0/80
Wire Fracture[1]	0/73	0/69	0/71	0/11	0/80
Extrusion/Erosion	0/79	0/75	0/73	0/11	0/80
Lumen Obstruction	0/77	0/72	0/68	0/10	0/80
Device Compression	0/79	0/75	0/73	0/11	0/80

Denominators used in calculation of percentages are number of subjects with an evaluable result.
Study period definitions: 1 Month (15-59 days), 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days), Total (15-911 days)
[1] Wire fracture was considered assessed and included in denominator if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed. All subjects were evaluated for wire fracture in at least one follow-up period.

Changes in maximum aneurysm diameter from baseline as measured by the Core Lab are summarized in **Table 28**. Per Core Lab-reported data, twenty-six (26) subjects in the 6 month visit window and twenty-seven (27) subjects in the 12 month visit window had an AAA decrease of ≥ 5 mm. There was one subject in both the 6 month visit window and 12 month visit window that had a Core Lab-reported AAA increase of ≥ 5 mm. No re-interventions were planned on the subject with the Core Lab-reported AAA increase of ≥ 5 mm and subject follow up is continuing.

Table 28. Change in Maximum Abdominal Aortic Diameter from Baseline

	6 Months	12 Months	24 Months
Number of Subjects with Available Data[1]	74	73	11
Change in Maximum Abdominal Aortic Diameter from Baseline (Core Lab)			
≥ 5mm Decrease	26(35.1%)	27(37.0%)	6(54.5%)
No Change	47(63.5%)	45(61.6%)	4(36.4%)
≥ 5mm Increase	1(1.4%)	1(1.4%)	1(9.1%)

Study period definitions: 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days)
If multiple observations are contained within a single study window, the observation closest to the target study window date is used.
[1] Subjects must have a baseline (1 month) and a post-baseline measurement to be available for evaluation.

Table 29 summarizes site-reported and CEC adjudicated re-interventions. Two (2) subjects were adjudicated by the CEC to have experienced a re-intervention including a coil embolization and a self-expanding bare metal stent. Coil embolization was performed on one subject to treat a Type II endoleak on POD 222. The other subject had a stenosis of the right iliac limb distal to the endograft which was treated with a bare metal self-expanding stent on POD 44. Events for both subjects resolved without sequelae.

Table 29. Summary of Reinterventions Adjudicated by CEC by Time Window

	Post Treatment Follow-up Period						
	Procedure	**Post-Procedure**	**1 Month**	**6 Months**	**12 Months**	**24 Months**	**Total**
Number of Subjects	80	80	80	79	79	19	80
Subjects with Any Reintervention Adjudicated by CEC	0(0%)	0(0%)	1(1.3%)	1(1.3%)	1(1.3%)	0(0%)	2(2.5%)
Conversion to open repair	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Open Surgical Repair without EXCC Device Explant	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Glue (fibrin, polymer, etc.)	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
PTA	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Stent	-	-	1(1.3%)	0(0%)	0(0%)	-	1(1.3%)
Thrombectomy	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Endostaples	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Stent Graft – Thoracic	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Stent Graft – Abdominal, Proximal Extension	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Stent Graft – Abdominal, Interdevice Junction Coverage	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Stent Graft – Abdominal, Distal Extension	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Stent Graft – Peripheral	-	-	0(0%)	0(0%)	0(0%)	-	0(0%)
Embolization	-	-	0(0%)	1(1.3%)	1(1.3%)	-	1(1.3%)
Other surgery, treatment, or procedure	-	-	0(0%)	0(0%)	1(1.3%)	-	1(1.3%)

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval.

3. Subgroup Analyses

The following preoperative characteristic was evaluated for potential association with outcomes: sex.

No primary safety endpoint events were observed in this study. One effectiveness endpoint event occurred out of 59 male subjects (98.3% free from event), while the 7 female subjects (100.0%) were free from any effectiveness endpoint event. The proportion of subjects with effectiveness endpoint events was not significantly different across sexes (p-value = 1.0).

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 257 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. 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.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The primary effectiveness endpoint was analyzed for all eligible subjects. The percentage of subjects free from a primary effectiveness endpoint event was 98.5%. The lower confidence limit for freedom from primary effectiveness endpoint event was 93.0%, which exceeded the primary effectiveness endpoint performance goal of 80%.

Technical success was achieved in 100% of patients. There were no endoleaks, migration, rupture, or conversion to open repair. One patient had a sac expansion.

Based on the clinical endpoint outcomes presented above, there is reasonable assurance of the effectiveness of the GORE® EXCLUDER® Conformable AAA Device for the proposed intended use.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal testing, as well as data collected in a clinical study conducted to support PMA approval as described above. The percentage of subjects free from a primary safety endpoint event was 100%. The lower confidence limit for freedom from primary safety endpoint events was 96.3%, which exceeded the performance goal of 79%.

There were 3 SAEs reported in the study through 3 years. These include an incision site ecchymosis, a right femoral artery pseudoaneurysm, and a Type II endoleak. There were no device releated SAEs or UADEs.

The outcomes presented above demonstrate a reasonable assurance of the safety of the GORE® EXCLUDER® Conformable AAA Device for the proposed intended use.

C. Benefit-Risk Determination

The probable benefits of the device are based on the data collected in a clinical study conducted to support PMA approval as described above. The EXCC device consists of standard endovascular graft technology, that incorporates design modifications into the commercially available GORE Excluder device.

In the Gore EXCC Short Neck Clinical Substudy, there were no endoleaks, migration, rupture, or conversion to open surgery. In addition the majority of patients had aneurysms that decreased or remained stable in diameter during follow-up.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The AEs reported under this study are consistent with other studies of endovascular grafts to treat AAA. Device-

related risks include aneurysm expansion, stent-graft occlusion, the need for secondary intervention and fracture of the stent.

There were only 6/80 site reported patients enrolled in the study with neck lengths between 10 and 15 mm. Given the unique safety concerns associated with endovascular repair of shorter neck length aneurysms, this data were inadequate to support approval of the device for patients with aneurysm neck lengths shorter than 15 mm. However, the study collected adequate data to demonstrate safety and effectiveness in patients with aneurysm neck lengths 15 mm and above.

1. Patient Perspectives

This submission either 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 patients with infrarenal abdominal aortic and aorto-iliac aneurysms, the probable benefits outweight the probable risks.

D. 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 EXCC device met its performance and design specifications.The clinical study met the pre-specified performance goals 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). The totality of this data supports that the performance of the EXCC device is consistent with previous, commercialized versions of GORE® EXCLUDER® AAA Endoprostheses and in-line with the expectations of a next generation abdominal stent-graft.

XIII. CDRH DECISION

CDRH issued an approval order on December 22, 2020. The final conditions of approval cited in the approval order are described below.

Gore has agreed to provide a Clinical Update to physician users at least annually. This update will include a brief description of the study design, study progress and the results available to date for clinical evaluations of the device (i.e., IDE study and sponsor initiated post-approval study(ies)). This clinical update should also include a brief description of any Class I and II recalls, links to any safety communications and

descriptions of any field safety notices sent by the sponsor to physician users worldwide. Additional learnings from commercial experience within and outside the United States, a summary of any explant analysis findings and a high level discussion of any critical publications that discuss safety and performance of the device is also to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

In addition to the Annual Report requirements, Gore has agreed to provide the following data in a post-approval study (PAS) report.

1. Continued Follow-up of the IDE Study Subjects: This is a prospective, single-arm, multi-center study that consists of continued follow-up of all available Short Neck Substudy subjects from the AAA 13-03 Pivotal study. A total of 80 subjects were enrolled in the study and remaining subjects will be followed annually for 5 years. Events reported through 5 years will include serious adverse events, all-cause mortality, aneurysm-related mortality, aneurysm rupture, secondary interventions, conversion to open surgery, losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (≥ 5 mm), stent graft migration (≥ 10 mm), all types of endoleaks, and other device-related events. No formal hypothesis testing will be performed for the longer-term follow-up. Outcomes will be reported using descriptive statistics annually.

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

XIV. 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 Requirements and Restrictions: See approval order.

XV. REFERENCES

Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg. 2002;35(5):1048-60.