December 17, 2021

Neuravi Ltd.
Niall Fox
Director of Regulatory Affairs
Block 3, Ballybrit Business Park
Galway, H91 K5YD
Ireland

Re: K212340
Trade/Device Name: EMBOGUARD Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: November 16, 2021
Received: November 17, 2021

Dear Niall Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212340

Device Name
EMBOGUARD™ Balloon Guide Catheter

Indications for Use *(Describe)*
EMBOGUARD Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovascular system. The balloon provides temporary vascular occlusion during angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval Devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K212340

I. SUBMITTER:

510(k) Owner: Neuravi Ltd.

Block 3, Ballybrit Business Park, Galway H91 K5YD, Ireland

Contact Person: Niall Fox

Director Regulatory Affairs

Tel: +353-91-394123

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Date Prepared: December 17, 2021

II. DEVICE

Trade Name of Device: EMBOGUARD™ Balloon Guide Catheter

Common Name of Device: Catheter, Percutaneous

Classification Name: 21 CFR 870.1250 – Class II

Product Code: QJP

III. PREDICATE DEVICE

8F FlowGate Balloon Guide Catheter (K153729)

IV. DEVICE DESCRIPTION

EMBOGUARD Balloon Guide Catheter is a dual lumen, braid-reinforced, variable stiffness catheter with an eccentric inflation lumen, a radiopaque marker on the distal end and a bifurcated luer hub on the proximal end. A compliant balloon is mounted on the distal end. The distal end of the device shaft has a hydrophilic coating. Balloon Guide Catheter dimensions are indicated on the product label.

V. INDICATIONS FOR USE

EMBOGUARD Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovascular system. The balloon provides temporary vascular occlusion during angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval Devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics of the EMBOGUARD Balloon Guide Catheter device in comparison to those of the predicate device is presented below.

Characteristics	Predicate Device 8F FlowGate Balloon Guide Catheter (K153729)	Subject Device EMBOGUARD™ Balloon Guide Catheter (K212340)	Comparison
Classification	Class II (21CFR 870.1250)	Class II (21CFR 870.1250)	Same
Device Classification Name	Catheter, Percutaneous	Catheter, Percutaneous	Same
Classification Product Code	DQY	QJP	Similar
Indications for Use	FlowGate Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.	EMBOGUARD Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovascular system. The balloon provides temporary vascular occlusion during angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval Devices.	Similar The subject device is indicated for use only in the neurovasculature.
Material	Commonly used medical grade plastics (nylon, PTFE, polyolefin, polyamide) and stainless steel	Commonly used medical grade plastics (nylon, PTFE, polycarbonate, polyurethane, polyolefin, polyblend) and stainless steel	Similar The differences do not raise new questions of safety and effectiveness. This is confirmed through biocompatibility and performance testing.

Reinforced Catheter Shaft	Stainless steel braid	Stainless steel braid	Same
Radiopaque Marker Band	Distal tip Pt-Ir marker band	Distal tip Pt-Ir marker band	Same
Radiopaque Marker location from Distal Tip	0.75mm	1.3mm	Similar Differences do not raise new questions of safety and effectiveness, and do not impact visibility under fluoroscopy. This is confirmed through radiopaque marker visualization as part of performance testing.
Radiopaque Marker Length	0.020”	0.031”	Similar Differences do not raise new questions of safety and effectiveness, and do not impact visibility under fluoroscopy. This is confirmed through radiopaque marker visualization as part of performance testing.
Compliant Balloon	Yes, silicone	Yes, polyblend	Similar Differences do not raise new questions of safety and effectiveness. Both materials are used for compliant balloons for intravascular use.
Effective Length	85 cm 95 cm	85 cm 95 cm	Same
Labelled Shaft Outer Diameter	8F (2.7 mm)	8F (2.8 mm)	Similar The differences do not raise new questions of safety and effectiveness. Compatibility with

			ancillary devices has been verified through the performance testing.
Labelled Shaft Inner Diameter	6.4F (0.084”)	6.6F (0.087”)	Similar The differences do not raise new questions of safety and effectiveness. Compatibility with ancillary devices has been verified through the performance testing.
Tip Shape	Straight	Straight	Same
Outer Coating	Not applicable	Hydrophilic Coating – Distal portion of the shaft	The difference does not raise new questions of safety and effectiveness. Hydrophilic coatings are commonly used to enhance lubricity of intravascular catheters.
Balloon Inflation Lumen	Coaxial	Non-coaxial	The difference does not raise new questions on safety and effectiveness. The balloon inflation lumen design and balloon performance have been evaluated through performance testing.
Accessory Devices Provided	Dilator (1) Rotating Hemostasis Valve (1) Tuohy Borst Valve with Sideport (1) Peel Away Sheath (1) Luer-Activated Valve (1) Extension Tubing (1)	Dilator (1) Rotating Hemostasis Valve (1) Tuohy Borst Valve with Sideport (1) Peel Away Sheath (1) Luer-Activated Valve (1)	Similar The differences do not raise new questions of safety and effectiveness.
How Supplied	Sterile, Single Use	Sterile, Single Use	Same
Sterilization Method	EtO	EtO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

VII. PERFORMANCE DATA

Biocompatibility Testing:

The biocompatibility evaluation for the EMBOGUARD Balloon Guide Catheter device was conducted in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" and FDA biocompatibility guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"."

The EMBOGUARD Balloon Guide Catheter device is categorized as an external communicating device with limited exposure with circulating blood (≤ 24 hours) per ISO 10993-1.

The biocompatibility evaluation included the following tests:

Test Name	Test Method	Results
Cytotoxicity	Tested in accordance with ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for *in vitro* cytotoxicity.	Pass Non-cytotoxic according to the pre-determined acceptance criteria.
Sensitization	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization. Kligman and Magnusson Maximisation Test.	Pass Did not elicit a sensitization response according to the pre-determined acceptance criteria.
Intracutaneous Irritation	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.	Pass Test requirements for intracutaneous reactivity were met according to the pre-determined acceptance criteria.
Systemic Toxicity: Systemic Injection Test	Tested in accordance with ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.	Pass Test requirements for systemic toxicity were met, according to the pre-determined acceptance criteria.
Systemic Toxicity: Material Mediated Pyrogenicity	Tested in accordance with ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity, and USP <151> Pyrogen Test.	Pass Non-pyrogenic, met the pre-determined acceptance criteria.

Hemocompatibility: Hemolysis Study	Tested in accordance with ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood. Tests for Hemolytic Properties, Direct and Indirect Methods.	Pass Non-hemolytic, met the pre-determined acceptance criteria.
Hemocompatibility: Complement Activation Study	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood. SC5b-9 Complement Activation.	Pass Does not activate the complement system, met the pre-determined acceptance criteria.
Hemocompatibility: Thrombogenicity Study	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood.	Pass Demonstrates similar thromboresistance characteristics as the control device, met the pre-determined acceptance criteria.
Genotoxicity: Bacterial Reverse Mutation Study	Tested in accordance with ISO 10993-3, Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity, and OECD 471, Guideline for Testing of Chemicals, Bacterial Reverse Mutation Test.	Pass Non-mutagenic according to the pre-determined acceptance criteria.
Genotoxicity: Mouse Lymphoma Assay	Tested in accordance with ISO 10993-3, Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity, and OECD Guideline for the Testing of Chemicals.	Pass Non-mutagenic according to the pre-determined acceptance criteria.

All biocompatibility tests completed met the pre-determined acceptance criteria as specified in the test protocol and in accordance with the requirements of the applicable standards.

Sterilization and Shelf Life:

The EMBOGUARD Balloon Guide Catheter device is labelled as a single-use, sterile device, with a shelf life of 1 year. The sterilization process for the EMBOGUARD Balloon Guide Catheter device has been successfully validated and process monitoring controls are in place to assure that the device is EO-sterilized to achieve a minimum SAL of 10^{-6}.

Shelf life studies have been conducted for the EMBOGUARD Balloon Guide Catheter device and establish that the product and packaging remain functional and sterile for the shelf life period of 1 year.

Bench Testing:

The results of design verification and validation testing conducted on the EMBOGUARD Balloon Guide Catheter device demonstrate that it performs as designed, fulfils all pre-determined product performance specification requirements, and is suitable for its intended use. The verification and validation test results demonstrate that EMBOGUARD Balloon Guide Catheter is substantially equivalent to the predicate device.

Specifically, the following bench tests were performed on the subject device:

Performance Bench Testing Summary			
Study Name	**Description**	**Reference Standard**	**Results**
Visual Inspection and Dimensional Verification	To demonstrate that the product meets the visual and dimensional specifications.	ISO 10555-1:2013, Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements ISO 10555-4:2013, Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters ISO 11070:2014/AMD 1:2018, Sterile Single-Use Intravascular Introducers, Dilators and Guidewires	Pass All samples met the pre-determined acceptance criteria.
Visual Surface Inspection	To demonstrate the product satisfies the visual surface requirements.	ISO 10555-1:2013 ISO 10555-4:2013 ISO 11070:2014/AMD 1:2018	Pass All samples met the pre-determined acceptance criteria.

Torque Durability	To demonstrate that the product is capable of 360 degrees of rotation of the hub while the distal tip is fixed in position.	FDA guidance for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters:2010; §VIII.A.10 Torque Strength	Pass All samples met the pre-determined acceptance criteria.
Torque to Failure	The number of rotations of the proximal hub required to initiate device failure, including separation, when the distal end is held stationary.	Characterization only FDA guidance Certain PTCA Catheters:2010 §VIII.A.10 Torque Strength	Pass The test samples met the pre-determined acceptance criteria.
Torque Transmission	To determine the torque transmission ratio.	Characterization only FDA guidance Certain PTCA Catheters:2010 §VIII.A.10 Torque Strength	The torque transmission at the tip has been characterized successfully after a minimum 720° hub rotation.
Tensile Strength	To demonstrate the product satisfies the tensile strength requirements for bonds and tip pull test.	ISO 10555-1:2013 ISO 11070:2014/AMD 1:2018 FDA guidance Certain PTCA Catheters:2010 §VIII.A.7, Catheter Bond Strength, A.8, Tip Pull Test	Pass All samples met the pre-determined acceptance criteria.
Flexibility and Kink Resistance	To demonstrate that the product has acceptable flexibility and kink resistance when wrapped around a series of mandrels.	FDA guidance Certain PTCA Catheters:2010 §VIII.A.9 Flexibility and Kink Test	Pass All samples met the pre-determined acceptance criteria.

Kink to Failure	To determine the bend radius at which catheter kink occurs, as it is bent around mandrels of decreasing radii.	Characterization only FDA guidance Certain PTCA Catheters:2010 §VIII.A.9 Flexibility and Kink Test	The kink to failure has been characterized at different sections down to a 2.5mm mandrel.
Catheter Lubricity and Durability	To demonstrate that the product meets coating lubricity and durability specifications.	N/A	Pass All samples met the pre-determined acceptance criteria.
Coating Length and Location	To demonstrate that the product meets coating length and location specifications.	N/A	Pass All samples met the pre-determined acceptance criteria.
Particulates	This study was conducted to determine the quantity and size of particles generated during simulated use.	Characterization only AAMI TIR42:2010, Evaluation of Particulates Associated with Vascular Medical Devices ASTM F2743-11: 2010, Standard Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems USP <788> Particulate Matter in Injections	Pass The particulates from the subject device and cleared controls were evaluated and found comparable.
Coating Integrity	To characterize the coating under specified magnification pre- and post-simulated use.	Characterization only FDA guidance Certain PTCA Catheters:2010 §VIII.A.12 Coating Integrity	Coating has been characterized under specified magnification pre- and post-simulated use.
Radiopacity	To determine the radiopaque characteristics of the device and dilator.	ASTM F640-20, Standard Test Methods for Determining Radiopacity for Medical Use	Pass All samples met the pre-determined acceptance criteria.

Simulated Use	To evaluate device performance in simulated anatomy in relation to the key steps involved in the clinical procedure.	N/A	Pass All samples met the pre-determined acceptance criteria.
Simulated Clot Retrieval Testing	To evaluate device performance (including clot retrieval performance) in simulated anatomy in relation to the key steps involved in the clinical procedure.	N/A	Pass All samples met the pre-determined acceptance criteria.
User Evaluation	To evaluate device performance in simulated anatomy in relation to the key steps involved in the clinical procedure.	N/A	Pass All samples met the pre-determined acceptance criteria.
Catheter Deliverability and Withdrawal Force	To demonstrate that the device meets the required tracking force specification.	N/A	Pass All samples met the pre-determined acceptance criteria.
Cather Luer Hub Dimensional and Performance Testing	To demonstrate that the product meets the requirements for small bore connectors.	ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications — Part 7, Connectors for intravascular or hypodermic applications ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods ISO 594-1:1986, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements ISO 594-2:1998, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings	Pass All samples met the pre-determined acceptance criteria.

Inner Lumen Integrity - Pressure	To demonstrate that the product meets the pressure requirements.	ISO 10555-1:2013 FDA guidance Certain PTCA Catheters:2010 §VIII.B.1 Catheter Body Burst Pressure	Pass All samples met the pre-determined acceptance criteria.
Inner Lumen Integrity - Aspiration	To demonstrate that the product meets the aspiration air leakage requirements and will not collapse under aspiration.	ISO 10555-1:2013	Pass All samples met the pre-determined acceptance criteria.
Hub Shaft Pressure Integrity	To demonstrate that the device shaft meets the minimum inner diameter specification up to 1138kPa internal pressure through hub's inflation luer.	ISO 10555-1:2013 FDA guidance Certain PTCA Catheters:2010 §VIII.B.1 Catheter Body Burst Pressure	Pass All samples met the pre-determined acceptance criteria.
Introducer Sheath Compatibility (Insertion and Withdrawal)	To demonstrate that the product meets the required insertion and withdrawal force without product damage.	N/A	Pass All samples met the pre-determined acceptance criteria.
Introducer Sheath Compatibility (Re-insertion and Re-withdrawal)	To demonstrate device integrity is maintained post re-insertion and re-withdrawal.	N/A	Pass All samples met the pre-determined acceptance criteria.
Tip Stiffness	To demonstrate that the stiffness of the distal end of the	N/A	Pass All samples met the pre-

	product is similar to predicate device.		determined acceptance criteria.
Balloon Location	To demonstrate balloon meets the balloon location specification.	ISO 10555-4:2013	Pass All samples met the pre-determined acceptance criteria.
Balloon Inflation / Deflation	To demonstrate balloon meets the inflation and deflation time specifications.	ISO 10555-4:2013 FDA guidance Certain PTCA Catheters:2010 §VIII.A.6 Balloon Inflation and Deflation Time	Pass All samples met the pre-determined acceptance criteria.
Balloon Fatigue	To demonstrate that there is no degradation of the balloon after 20 inflation cycles.	ISO 10555-4:2013 FDA guidance Certain PTCA Catheters:2010 §VIII.A.4 Balloon Fatigue	Pass All samples met the pre-determined acceptance criteria.
Balloon OD and Compliance	To demonstrate that the product meets the maximum recommended inflation volume vs balloon diameter specifications.	ISO 10555-4:2013 FDA guidance Certain PTCA Catheters:2010 §VIII.A.5 Balloon Compliance	Pass All samples met the pre- determined acceptance criteria.
Balloon Concentricity	To demonstrate that the product meets the balloon diameter specifications on each side at the recommended inflation volume when rotated 360°.	ISO 10555-4:2013	Pass All samples met the pre-determined acceptance criteria.

Balloon Burst	To demonstrate that the balloon is capable of withstanding an injection volume of 2x and 2.5x recommended inflation volume.	ISO 10555-4:2013	Pass All samples met the pre-determined acceptance criteria.
Conditioning, Distribution, and Shelf Life Aging - Device	To demonstrate the device met all specifications at both baseline and following accelerated aging to a 1-year shelf life equivalent.	Evaluation of device following accelerated aging to a 1-year shelf life equivalent	Pass All samples met the pre- determined acceptance criteria.
Conditioning, Distribution, and Shelf Life Aging - Packaging	Evaluation of packaging strength and integrity at both baseline and following accelerated aging to a 1-year shelf life equivalent.	ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Pass All samples met the pre- determined acceptance criteria.
Visual Inspection Packaging and Labeling	To demonstrate that the product meets the packaging and labeling visual and adherence Requirements.	N/A	Pass All samples met the pre-determined acceptance criteria.
Dilator			
System Visual Inspection	To demonstrate that the product meets the visual and dimensional. specifications.	ISO 10555-1 ISO 10555-4	Pass All samples met the pre-determined acceptance criteria.

Effective Length	To demonstrate that the product meets the visual and dimensional specifications.	ISO 11070	Pass All samples met the pre-determined acceptance criteria.
Outer Diameter			
Inner Diameter			
Taper Diameter			
Tensile Strength	To demonstrate that the dilator withstands peak tensile strength.	ISO 10555-1 ISO 11070 FDA guidance Certain PTCA Catheters:2010	
Kink Resistance	To demonstrate that there are no kinks, defects or damage.	FDA guidance Certain PTCA Catheters:2010	
Dilator Hub Luer Dimensional & Performance Requirements			
Luer Dimensional	To demonstrate that the product meets the dimensional specifications.	ISO 80369-7	Pass All samples met the pre-determined acceptance criteria.
Fluid Leakage by Pressure Decay	To demonstrate that the luer lock connector does not leak while subjected to applied pressure.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Sub-atmospheric Pressure Air Leakage		ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Stress Cracking	To demonstrate that the luer lock connector does not crack when subjected to axial force and torque.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Resistance to Separation from Axial Load	To demonstrate that the luer lock connector does not separate from the reference connector while subjected to a disconnection applied axial force.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.

Resistance to Separation from Unscrewing	To demonstrate that the luer lock connector does not override the threads of a reference connector while subjected to unscrewing torque.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Resistance to Overriding	To demonstrate that the luer lock connector does not override the threads of a reference connector while subjected to applied torque.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Torque Durability	To demonstrate that there is no separation of the dilator hub from the shaft or embolization after one complete rotation of the hub.	FDA guidance Certain PTCA Catheters:2010 Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling	Pass All samples met the pre-determined acceptance criteria.
Luer Activated Valve (LAV)			
Visual Inspection	To demonstrate that the LAV meets the visual specifications.	ISO 10555-1 ISO 10555-4 ISO 11070	Pass All samples met the pre-determined acceptance criteria.
Leak Test	To demonstrate that the LAV does not leak when used to inflate/deflate the balloon.	N/A	Pass All samples met the pre-determined acceptance criteria.
Activation	To demonstrate that that the LAV allows flow and does not leak when activated. To demonstrate that the LAV prevents flow and maintains balloon inflation when the syringe is removed.	N/A	Pass All samples met the pre-determined acceptance criteria.

LAV Luer Dimensional & Performance Requirements LAV Male & Female Luer			
Dimensional	To demonstrate that the LAV meets the dimensional specifications.	ISO 80369-7	Pass All samples met the pre-determined acceptance criteria.
Fluid Leakage by Pressure Decay	To demonstrate that the LAV connector does not leak under applied pressure.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Sub-atmospheric Pressure Air Leakage			
Stress Cracking	To demonstrate the LAV connector does not crack under specified axial force and torque.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Resistance to Separation from Axial Load	To demonstrate the LAV connector does not separate from the reference connector while subjected to a disconnection applied axial force.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Resistance to Separation from Unscrewing	To demonstrate the LAV connector does not separate from the reference connector while subjected to specified unscrewing torque.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Resistance to Overriding	To demonstrate that the luer lock connector does not override the threads of a reference connector while subjected to an applied torque.	ISO 80369-20	Pass All samples met the pre-determined acceptance criteria.
Rotating Hemostasis Valve (RHV)			
Visual	To demonstrate that		Pass

Inspection	the RHV meets the visual specifications.	ISO 10555-1 ISO 10555-4 ISO 11070	All samples met the pre-determined acceptance criteria.
ID (Male Luer)	To demonstrate the RHV meets the ID specification of the rigid male luer.	ISO 10555-1 ISO 10555-4 ISO 11070	Pass All samples met the pre-determined acceptance criteria.
ID (Compression Seal)	To demonstrate the RHV meets the ID specification of the compression seal.	ISO 10555-1 ISO 10555-4 ISO 11070	Pass All samples met the pre-determined acceptance criteria.
ID (Side Port)	To demonstrate the RHV meets the ID specification of the side port.	ISO 10555-1 ISO 10555-4 ISO 11070	Pass All samples met the pre-determined acceptance criteria.
Seal Integrity (Pressure)	To demonstrate the RHV does not leak or collapse under pressure.	ISO 10555-1	Pass All samples met the pre-determined acceptance criteria.
Seal Integrity (Aspiration)	To demonstrate the RHV does not leak or collapse under aspiration.	ISO 10555-1	Pass All samples met the pre-determined acceptance criteria.
RHV Hub Luer Dimensional & Performance			
Gauging	To demonstrate that RHV product meets the conical part of the lock fitting.	ISO 594-1	Pass All samples met the pre-determined acceptance criteria.
Liquid Leakage	To demonstrate that there is no leakage sufficient to form a falling drop.		

Air Leakage	To demonstrate that there is no sign of continued formation of air bubbles.	ISO 594-2	Pass All samples met the pre-determined acceptance criteria.
Separation Force	To demonstrate that the product fitting remains attached to the reference fitting.		
Unscrewing Torque			
Ease of Assembly	To demonstrate that the RHV meets the requirements for small bore connectors.		
Resistance to Overriding	To demonstrate the RHV fitting does not override the threads or lugs of the fitting.		
Stress Cracking	To demonstrate that the RHV withstands stress cracking of the fitting.	ISO 594-2	Pass All samples met the pre-determined acceptance criteria.

Animal Studies:

Acute animal study has been performed to assess the usability, effectiveness and safety of the EMBOGUARD Balloon Guide Catheter device compared to the predicate device in the swine model. Acute performance evaluated on Day 0 showed that the usability and performance of the EMBOGUARD Balloon Guide Catheter device was equivalent to that of the predicate device tested. Histological evaluation performed on treated vessels after 2-3 days demonstrated that the local and end organ tissue response was comparable between the EMBOGUARD Balloon Guide Catheter and the predicate device tested.

Clinical Studies:

No clinical studies were performed to demonstrate substantial equivalence.

CONCLUSIONS

The subject device has similar intended use and technological characteristics as the predicate device. The differences do not raise new questions of safety and effectiveness. Non-clinical studies conducted demonstrate that the EMBOGUARD Balloon Guide Catheter is substantially equivalent to the predicate device.