April 18, 2024

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

Re: K233924
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: March 22, 2024
Received: March 22, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233924

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

K233924

I. SUBMITTER:

510(k) Owner: Neuravi Ltd.

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

Contact Person: Niall Fox

Director of Regulatory Affairs

Tel: +353-91-394123

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Date Prepared: April 16th 2024

II. DEVICE

Trade Name of Device: EMBOGUARD™ Balloon Guide Catheter

Common Name of Device: Catheter, Percutaneous, Neurovasculature

Classification Name: 21 CFR 870.1250 – Class II

Product Code: QJP

III. PREDICATE DEVICES

EMBOGUARD™ Balloon Guide Catheter (K212340)

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. The device specifications are unchanged in comparison to the predicate devices. There is a change in the shafts' Pebax jacket materials blend of Pebax, colorant mix and addition of colorant carrier. The forming process of the catheter inner lumen liner material has also changed.

Characteristics	Predicate Device: EMBOGUARD™ Balloon Guide Catheter	Subject Device: EMBOGUARD™ Balloon Guide Catheter
510(k) Number	K212340	K233924
Classification	Class II, 21 CFR 870.1250	Same as Predicate Device
Device Classification Name	Catheter, Percutaneous, Neurovasculature	Same as Predicate Device
Classification Product Code	QJP	Same as Predicate Device
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.	Same as Predicate Device
Materials	Commonly used medical grade plastics (nylon, PTFE, polycarbonate, polyurethane, polyolefin, polyblend) and stainless steel	Same as Predicate Device
Shaft Outer Jacket Distal Segment (1) Pebax 35D Jacket 0.004" W/T	Pebax 3533 SA01 MED Techmer Blue/Black (PM50167E1) Irganox 1010 Tinuvin 622	Pebax 3533 SA01 MED Pebax 5533 SA01 MED (colorant carrier) CSRM016 Pigment Blue 36 CSRM037 Pigment Violet 23 CSRM035 Pigment Green 7 Irganox 1010 Tinuvin 622
Shaft Outer Jacket Distal Segment (2) Pebax 35D Jacket 0.005" W/T	Pebax 3533 SA01 MED Techmer Blue/Black (PM50167E1) Irganox 1010 Tinuvin 622	Pebax 3533 SA01 MED Pebax 5533 SA01 MED (colorant carrier) CSRM016 Pigment Blue 36 CSRM037 Pigment Violet 23 CSRM035 Pigment Green 7 Irganox 1010 Tinuvin 622
Shaft Outer Jacket Distal Segment (3) Pebax 35/40D Jacket	Pebax 4033 SA01 MED Pebax 3533 SA01 MED Techmer Blue/Black (PM50167E1) Irganox 1010 Tinuvin 622	Pebax 5533 SA01 MED Pebax 3533 SA01 MED CSRM016 Pigment Blue 36 CSRM037 Pigment Violet 23 CSRM035 Pigment Green 7

Characteristics	Predicate Device: EMBOGUARD™ Balloon Guide Catheter	Subject Device: EMBOGUARD™ Balloon Guide Catheter
		Irganox 1010 Tinuvin 622
Shaft Outer Jacket Distal Segment (4) Pebax 40D Jacket	Pebax 4033 SA01 MED Techmer Blue/Black (PM50167E1) Irganox 1010 Tinuvin 622	Pebax 5533 SA01 MED Pebax 3533 SA01 MED CSRM016 Pigment Blue 36 CSRM037 Pigment Violet 23 CSRM035 Pigment Green 7 Irganox 1010 Tinuvin 622
Shaft Outer Jacket Distal Segment (5) Pebax 55D Jacket	Pebax 5533 SA01 MED Techmer Blue/Black (PM50167E1) Irganox 1010 Tinuvin 622	Pebax 5533 SA01 MED CSRM016 Pigment Blue 36 CSRM037 Pigment Violet 23 CSRM035 Pigment Green 7 Irganox 1010 Tinuvin 622
Shaft Outer Jacket Distal Segment (6) Pebax 72D Jacket	Pebax 7233 SA01 MED Techmer Blue/Black (PM50167E1) Irganox 1010 Tinuvin 622	Pebax 7233 SA01 MED Pebax 5533 SA01 MED (colorant carrier) CSRM016 Pigment Blue 36 CSRM037 Pigment Violet 23 CSRM035 Pigment Green 7 Irganox 1010 Tinuvin 622
Inner Lumen Liner	RAM extruded forming process; method by which the liner is formed into its tubular shape	Film cast forming process; method by which the liner is formed into its tubular shape
Reinforced Catheter Shaft	Stainless steel braid	Same as Predicate Device
Radiopaque Marker Band	Distal tip Pt-Ir marker band	Same as Predicate Device
Radiopaque Marker Location from Distal Tip	1.3 mm	Same as Predicate Device
Radiopaque Marker Length	0.031”	Same as Predicate Device
Compliant Balloon	Yes, polyblend	Same as Predicate Device
Effective Length	85 cm, 95 cm	Same as Predicate Device
Labelled Shaft Outer Diameter	8F (2.8 mm)	Same as Predicate Device
Labelled Shaft Inner Diameter	6.6F (0.087”)	Same as Predicate Device
Tip Shape	Straight	Same as Predicate Device
Outer Coating	Hydrophilic Coating – Distal portion of the shaft	Same as Predicate Device

Characteristics	Predicate Device: EMBOGUARD™ Balloon Guide Catheter	Subject Device: EMBOGUARD™ Balloon Guide Catheter
Balloon Inflation Lumen	Non-coaxial	Same as Predicate Device
Accessory Devices Provided	Dilator (1) Rotating Hemostasis Valve (1) Peel Away Sheath (1) Luer-Activated Valve (1)	Same as Predicate Device
How Supplied	Sterile, Single Use	Same as Predicate Device
Sterilization Method	EtO	Same as Predicate Device
Sterility Assurance Level	10^{-6}	Same as Predicate Device
Shelf Life	1 year	1 year

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. 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. The biocompatibility evaluation included the following tests.

Biocompatibility Testing		
Test	**Test Method Summary**	**Results**
Cytotoxicity Study	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 Study	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.
Acute Systemic Toxicity	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.
Pyrogenicity – Material-Mediated Rabbit Pyrogen	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.
Hemolysis Study	Tested in accordance 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.
SC5b-9 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.
ASTM Partial Thromboplastin Time (PTT)	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 characteristic as the control device, met the pre-determined acceptance criteria.

Platelet and Leukocyte Count	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 characteristic as the control device, met the pre-determined acceptance criteria.

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. Previous testing with the predicate device has demonstrated that 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 sterility assurance level (SAL) of 10^{-6}. The changes made to the EMBOGUARD Balloon Guide Catheter do not impact its sterilization.

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

***In Vitro* (Bench) Testing:**

Performance bench testing was conducted according to existing test methods previously reviewed by FDA in the predicate submission (K212340). A description of each performance test used to support substantial equivalence determination is presented below.

Performance Bench Testing			
Test	**Description**	**Reference Standard**	**Results**
Balloon Inflation / Deflation Time	To demonstrate the balloon meets the inflation and deflation time specifications.	FDA guidance Certain PTCA Catheters:2010; §VIII.A6 Balloon Inflation and Deflation Time	Pass All samples met the pre-determined acceptance criteria.
Balloon Fatigue	To demonstrate that there is no leakage or damage to the balloon after 20 inflation cycles.	FDA guidance Certain PTCA Catheters:2010; §VIII.A4 Balloon Fatigue (Repeat Balloon Inflations)	Pass All samples met the pre-determined acceptance criteria.
Balloon Outer Diameter (OD) and Compliance	To demonstrate that the product meets the maximum recommended inflation volume vs. balloon diameter specifications.	FDA guidance Certain PTCA Catheters:2010; §VIII.A5 Balloon Compliance (Diameters vs. Pressure)	Pass All samples met the pre-determined acceptance criteria.

Balloon Concentricity	To demonstrate that the product meets the balloon diameter specification on each side at the recommended inflation volume when rotated 360°.	FDA guidance Certain PTCA Catheters:2010; §VIII.A5 Balloon Compliance (Diameter vs. Pressure)	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.	N/A	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.
Inner Lumen Integrity - Pressure	To demonstrate that the product meets the pressure requirements.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements 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 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements FDA guidance Certain PTCA Catheters:2010; §VIII.B.1 Catheter Body Burst Pressure	Pass All samples met the pre-determined acceptance criteria.
Catheter Deliverability and Withdrawal Force	To demonstrate that device meets the required tracking force specification.	N/A	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	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 Certain PTCA Catheters:2010; §VIII.A.10 Torque Strength FDA guidance "Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling":2019	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.	FDA guidance "Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling":2019 FDA guidance Certain PTCA Catheters:2010; §VIII.A.10 Torque Strength	Pass All samples met the pre-determined acceptance criteria.
Visual Inspection	To demonstrate the product satisfies the visual surface requirements.	ISO 10555-1:2013 Intravascular Catheters-Sterile and single-use catheters – Part 1: General requirements	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	Pass The particulates from the subject device and the predicate were evaluated and found comparable.
Tensile Strength	To demonstrate the product satisfies the tensile strength requirements for bonds and tip pull test.	ISO 10555-1:2013 Intravascular Catheters-Sterile and single-use catheters – Part 1: General requirements. FDA guidance Certain PTCA Catheters:2010; §VIII.A.7 Catheter Bond Strength, §VIII.A.8 Tip Pull Test	Pass All samples met the predetermined acceptance criteria.
Tip Stiffness	To demonstrate that the stiffness of the distal end of the product is similar to predicate device.	N/A	Pass The tip deflection force of the subject device was evaluated and found comparable to the predicate.

Animal Studies:

No animal study was deemed necessary to evaluate the changes to the subject device and demonstrate substantial equivalence to the predicate device.

Clinical Studies:

No clinical study was deemed necessary to demonstrate substantial equivalence between the subject and predicate device.

VIII. CONCLUSIONS

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