September 25, 2025

Neuravi Limited
Marie Seoighe
Senior Regulatory Affairs Specialist
Block 3,
Ballybrit Business Park
Galway H91 K5YD,
Ireland

Re: K251789
Trade/Device Name: EMBOTRAP III Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: August 27, 2025
Received: August 28, 2025

Dear Marie Seoighe:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, PhD
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)*
K251789

Device Name
EMBOTRAP III Revascularization Device

Indications for Use *(Describe)*
The EMBOTRAP III Revascularization Device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K251789

I. SUBMITTER:

510(k) Owner: Neuravi Ltd.

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

Contact Person: Marie Seoighe

Senior Regulatory Affairs Specialist

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Date Prepared: September 24, 2025

II. DEVICE

Trade Name of Device: EMBOTRAP™ III Revascularization Device

Common Name of Device: Catheter, Thrombus Retriever

Classification Name: 21 CFR 870.1250 – Class II

Product Code: NRY

III. PREDICATE AND REFERENCE DEVICES

Predicate: EMBOTRAP™III Revascularization Device (K212908, October 13, 2021)
Reference: EMBOTRAP™III Revascularization Device (K193063, July 14, 2020)

IV. DEVICE DESCRIPTION

The EMBOTRAP™ III Revascularization Device is composed of a retrievable, self-expanding, Nitinol shaped section at the distal end of a tapered Nitinol shaft. It is designed to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. The EMBOTRAP™ III Revascularization Device is supplied sterile and is intended for single-use only by physicians trained in neuro-interventional catheterization and the treatment of ischemic stroke.

V. INDICATIONS FOR USE

The EMBOTRAP™ III Revascularization Device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics of the EMBOTRAP™ III device in comparison to those of the predicate device is presented below. The change in the subject submission is to add green PTFE coated shaft component material to the EMBOTRAP™ III device.

Characteristics	Predicate Device	Subject Device
	EMBOTRAP III **(5 x 22 mm, 5 x 37 mm, 6.5 x 45 mm)**	**EMBOTRAP III** **(5 x 22 mm, 5 x 37 mm, 6.5 x 45 mm)**
Manufacturer	Neuravi Ltd.	Same
510(k) Number	K212908	K251789
Classification	Class II (21 CFR 870.1250)	Same
Device Classification Name	Catheter, Thrombus Retriever	Same
Classification Product Code	NRY	Same
Indication for Use	The EMBOTRAP III Revascularization Device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	The EMBOTRAP III Revascularization Device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.
Target Population	Patients with symptoms of an ischemic stroke within 8 hours of symptom onset, who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	Patients with symptoms of an ischemic stroke within 8 hours of symptom onset, who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.
Microcatheter Compatibility as per Applicable Instructions for Use	COMPATIBILITY: "Microcatheter: The Device should be introduced through microcatheters indicated for the delivery of therapeutic devices in the neurovasculature with an internal diameter (ID) of 0.021" – 0.027" (0.53 mm – 0.69 mm), e.g., PROWLER SELECT PLUS, PROWLER EX, Trevo 18, Headway 21, Velocity 025, Phenom 27 and Marksman 27 microcatheters. Performance of the Device with other microcatheters that have not been evaluated may be different."	Same

Characteristics	Predicate Device **EMBOTRAP III** **(5 x 22 mm, 5 x 37 mm, 6.5 x 45 mm)**	Subject Device **EMBOTRAP III** **(5 x 22 mm, 5 x 37 mm, 6.5 x 45 mm)**
Design/Technological Principles	Nitinol guidewire like shaft; Retrievable, self-expanding Nitinol shaped section	Same
Distal End (Retriever) Design	Bi-layer tubular design with a tapered distal end with tip 5 x 22 mm  5 x 37 mm  6.5 X 45 mm 	Same
Shaped Section & Shaft Wire	Nitinol	Same
Distal Marker/Coil	Platinum/Tungsten Coil	Same
Proximal Marker/Coil	Platinum/Tungsten Coil	Same
Shaft Coating	Hydrophobic Blue PTFE Coating	Hydrophobic Green PTFE Coating Similar Differences do not raise new questions of safety or effectiveness.
Pebax Jacket	Pebax 7233 3065 Blue Colorant	Same

Characteristics	Predicate Device	Subject Device
	EMBOTRAP III **(5 x 22 mm, 5 x 37 mm, 6.5 x 45 mm)**	**EMBOTRAP III** **(5 x 22 mm, 5 x 37 mm, 6.5 x 45 mm)**
Size(s) Offered **(Retriever Diameter × Length)**	5 × 22 mm, 5 × 37 mm, 6.5 x 45mm	Same
Device Length	194 cm, 195 cm & 196 cm (Labeled Overall length)	Same
Minimum Microcatheter ID	0.021" - 0.027"	Same
Key Principles of Operation	The device is used in the neurovasculature to restore blood flow in patients experiencing ischemic stroke.	Same
No. of Passes per Device IFU	3 / Device & Vessel	Same
How Suppled	Sterile/Single Use	Same
Sterilization Method	Ethylene Oxide	Same

VII. PERFORMANCE DATA

Biocompatibility Testing:

The biocompatibility evaluation for the EMBOTRAP™ III Revascularization Device was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" and the 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"," (June 16, 2016). Per ISO 10993-1, the EMBOTRAP™ III device is categorized as an external communicating device with limited exposure, i.e. whose direct contact with circulating blood is ≤24 hours.

The biocompatibility evaluation included the following tests:

Biocompatibility Testing		
Endpoint and Test	**Test Method Summary**	**Results**
Cytotoxicity MEM Elution in L929 cells	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 Guinea Pig Maximization	Tested in accordance with ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.	Pass Did not elicit a sensitization response according to the pre-determined acceptance criteria.
Irritation Intracutaneous Reactivity in Rabbits	Tested in accordance with ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation.	Pass Test requirements for intracutaneous reactivity were met according to the pre-determined acceptance criteria.
Acute Systemic Toxicity Mouse Injection Study	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.

Biocompatibility Testing		
Endpoint and Test	**Test Method Summary**	**Results**
Material-Mediated Pyrogenicity –Rabbit Pyrogen Test	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 ASTM Direct and Indirect (Extract) 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.	Pass Non-hemolytic, met the pre-determined acceptance criteria.
Hemocompatibility 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.	Pass Does not activate the complement system, met the pre-determined acceptance criteria.
Hemocompatibility Thrombogenicity 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.
Hemocompatibility Thrombogenicity 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.
Hemocompatibility Thrombogenicity Visual Comparative Assessment	The geometry and surface characteristics of the subject device and predicate device were visually inspected under magnification to ensure no differences were identified that may impact the thrombogenicity risk of the subject device.	Pass Demonstrates similar thromboresistance characteristic as the control device.

Sterilization and Shelf Life:

The EMBOTRAP™ III device is labelled as a single-use, sterile device, with a shelf life of 3 years. Previous testing with the predicate device has demonstrated that the sterilization process for the EMBOTRAP III 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 subject EMBOTRAP™ III device do not impact its sterilization or established shelf-life. Shelf-life studies have been conducted on the EMBOTRAP III device and established that the product and packaging remain functional and sterile for the shelf-life period of 3 years.

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

Testing was conducted according to existing design controls and test methods previously reviewed by FDA in relevant prior submissions. Performance tests conducted and used to support substantial equivalence determination are presented below.

Performance Testing		
Test	**Test Method Summary**	**Results**
Particulate Testing	To evaluate and compare the quantity and size of particles generated by the subject device during simulated device delivery in a tortuous anatomical model versus particles generated by the predicate.	Particle generation was comparable between the subject device and predicate device.
Durability Testing	The device was evaluated for damage after delivery and withdrawal of the subject device beyond the recommended number of passes and re-sheathings recommended in the instructions for use.	Pass All required specifications were met. Durability performance of the subject device is comparable to that of the predicate device.
Kink Resistance	Kink resistance of the entire device (shaft and shaped section) was evaluated using a representative worst-case device model, which was wrapped around a series of mandrels of decreasing radii until permanent deformation was observed or until the smallest radius was used.	Pass All required specifications were met. Kink resistance of the subject device is comparable to that of the predicate device.
Coating Integrity	Coating integrity of the subject device was evaluated on a representative (worst-case) device model by examining the shaft coating under microscopy pre- and post- simulated use.	Pass All required specifications were met. Coating integrity of the subject device is comparable to that of the predicate device.

Performance Testing		
Test	**Test Method Summary**	**Results**
Delivery Force	A representative (worst-case) device model was evaluated in a tortuous track model to determine the force required to deliver the subject device in a microcatheter.	Pass All required specifications were met. Delivery force of the subject device is comparable to that of the predicate device.

Animal Studies:

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

Clinical Studies:

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the subject device. Substantial equivalence of the subject device has been established to the predicate device through the results of bench and biocompatibility testing.

VIII. CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as the predicate device. The difference in technological characteristics does not raise new questions of safety or effectiveness. Non-clinical studies conducted demonstrate that the EMBOTRAP™III Revascularization Device is substantially equivalent to the predicate device.