October 13, 2021

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

Re: K212908
Trade/Device Name: EmboTrap II Revascularization Device; EMBOTRAP III Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: September 10, 2021
Received: September 13, 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)*
K212908

Device Name
EmboTrap II Revascularization Device
EMBOTRAP III Revascularization Device

Indications for Use *(Describe)*
The EmboTrap II 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA 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.

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510(k) Summary

K212908

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

E-mail: nfox5@its.jnj.com

Date Prepared: October 07, 2021

II. DEVICE

Trade Name of Device: EmboTrap II Revascularization 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 DEVICES

EmboTrap II Revascularization Device (K173452, May 9, 2018)

EMBOTRAP™ III Revascularization Device (K193063, July 14, 2020)

EMBOTRAP™ III Revascularization Device (K211338, July 30, 2021)

IV. DEVICE DESCRIPTION

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

V. INDICATIONS FOR USE

The EmboTrap II 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics of the EmboTrap® II and EMBOTRAP™ III devices in comparison to those of the predicate devices is presented below. The technological characteristics (e.g., principal device materials, design, dimensions) are unchanged in comparison to the predicate devices. The change in the subject submission is to add PROWLER SELECT PLUS and PROWLER EX Microcatheters to the device labelling as compatible with the EmboTrap II and EMBOTRAP III devices.

Characteristics	Predicate Devices Referenced in this Submission			Subject Device	Subject Device
	EmboTrap II (5 x 21 mm and 5 x 33 mm)	**EMBOTRAP III (5 x 22 mm and 5 x 37 mm)**	**EMBOTRAP III (6.5 x 45 mm)**	**EmboTrap II (5 x 21 mm and 5 x 33 mm)**	**EMBOTRAP III (5 x 22 mm and 5 x 37 mm, 6.5 x 45 mm)**
Manufacturer	**Neuravi Ltd.**	**Neuravi Ltd.**	**Neuravi Ltd.**	**Same as EmboTrap II**	**Same as EMBOTRAP III**
510(k) Number	K173452	K193063	K211338	**K212908**	**K212908**
Classification	Class II (21CFR 870.1250)			**Same as EmboTrap II**	**Same as EMBOTRAP III**
Device Classification Name	Catheter, Thrombus Retriever			**Same as EmboTrap II**	**Same as EMBOTRAP III**
Classification Product Code	NRY			**Same as EmboTrap II**	**Same as EMBOTRAP III**
Indication for Use	The EmboTrap II 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.		**Same as EmboTrap II**	**Same as EMBOTRAP III**
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			**Same as EmboTrap II**	**Same as EMBOTRAP III**

Characteristics	Predicate Devices Referenced in this Submission			Subject Device	Subject Device
	EmboTrap II (5 x 21 mm and 5 x 33 mm)	**EMBOTRAP III (5 x 22 mm and 5 x 37 mm)**	**EMBOTRAP III (6.5 x 45 mm)**	**EmboTrap II (5 x 21 mm and 5 x 33 mm)**	**EMBOTRAP III (5 x 22 mm and 5 x 37 mm, 6.5 x 45 mm)**
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 of a size "18" or larger, with a minimum internal diameter of 0.021" and an overall length of not more than 155 cm, e.g., Trevo 18, Merci 18L, Headway 21, Cantata, Velocity 025, Marksman 27 and Excelsior XT-27 microcatheters. Performance of the Device with other microcatheters that have not been evaluated may be different."	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., 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."		**Similar** Differences do not raise new questions of safety and effectiveness, EMBOTRAP device has been tested for compatibility with PROWLER SELECT PLUS and PROWLER EX Microcatheters: "Microcatheter: The Device should be introduced through microcatheters indicated for the delivery of therapeutic devices in the neurovasculature of a size "18" or larger, with a minimum internal diameter of 0.021" and an overall length of not more than 155 cm, e.g. PROWLER SELECT PLUS, PROWLER EX, Trevo 18, Merci 18L, Headway 21, Cantata, Velocity 025 Marksman 27 and Excelsior XT-27 microcatheters. Performance of the Device with other microcatheters that have not been evaluated may be different."	**Similar** Differences do not raise new questions of safety and effectiveness, EMBOTRAP device has been tested for compatibility with PROWLER SELECT PLUS and PROWLER EX Microcatheters: "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."
Design/Technological Principles	Retrievable, self-expanding Nitinol shaped section Nitinol guidewire like shaft			**Same as EmboTrap II**	**Same as EMBOTRAP III**

Characteristics	Predicate Devices Referenced in this Submission			Subject Device	Subject Device
	EmboTrap II (5 x 21 mm and 5 x 33 mm)	**EMBOTRAP III (5 x 22 mm and 5 x 37 mm)**	**EMBOTRAP III (6.5 x 45 mm)**	**EmboTrap II (5 x 21 mm and 5 x 33 mm)**	**EMBOTRAP III (5 x 22 mm and 5 x 37 mm, 6.5 x 45 mm)**
Distal End (Retriever) Design	**Bi-layer tubular design with a tapered distal end with tip**	**Bi-layer tubular design with a tapered distal end with tip**	**Bi-layer tubular design with a tapered distal end with tip**	**Same as EmboTrap II**	**Same as EMBOTRAP III**
	5 x 21 mm  5 x 33 mm 	5 x 22 mm  5 x 37 mm 		**Same as EmboTrap II**	**Same as EMBOTRAP III**
Principal Device Materials					
Shaped Section & Shaft Wire	Nitinol	Nitinol	Nitinol	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Distal Marker/Coil	Platinum/Tungsten Coil	Platinum/Tungsten Coil	Platinum/Tungsten Coil	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Proximal Marker/Coil	Platinum/Tungsten Coil	Platinum/Tungsten Coil	Platinum/Tungsten Coil	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Shaft Coating	Hydrophobic PTFE Coating	Hydrophobic PTFE Coating	Hydrophobic PTFE Coating	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Design Characteristics & Technology					
Size(s) Offered (Retriever Diameter × Length)	5×21 mm, 5×33 mm	5×22 mm, 5×37 mm	6.5x45 mm	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Device Length	194 cm, 195 cm (Labeled Overall length)	194 cm, 195 cm (Labeled Overall length)	196 cm (Labeled Overall length)	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Minimum Microcatheter ID	0.021”	0.021”-0.027”	0.021”-0.027”	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Key Principles of Operation	The device is used in the neurovasculature to restore blood flow in patients experiencing ischemic stroke			**Same as EmboTrap II**	**Same as EMBOTRAP III**
No. of passes/device IFU	3 / Device & Vessel	3 / Device & Vessel	3 / Device & Vessel	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Additional Characteristics					
How suppled	Sterile/Single Use	Sterile/Single Use	Sterile/Single Use	**Same as EmboTrap II**	**Same as EMBOTRAP III**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	**Same as EmboTrap II**	**Same as EMBOTRAP III**

VII. PERFORMANCE DATA

Biocompatibility Testing:

N/A - Changes do not impact biocompatibility.

Sterilization and Shelf Life:

N/A - Changes do not impact sterilization and established shelf-life of the product.

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

Bench testing was conducted according to existing design controls and protocols / test methods previously reviewed by the FDA in relevant prior submissions. Description of each performance test used to support substantial equivalence determination is presented below.

Performance Testing		
Test	**Test Method Summary**	**Results**
Simulated use testing in a tortuous anatomical model	To provide evidence that the PROWLER microcatheters could safely and effectively deliver the EMBOTRAP devices to the neurovasculature.	Test sample microcatheters successfully delivered EMBOTRAP devices.
Particulate testing	To evaluate and compare the quantity and size of particles generated by the EMBOTRAP devices during simulated device delivery in a tortuous anatomical model with the PROWLER SELECT PLUS Microcatheter versus particles generated by an applicable reference cleared microcatheter.	Particle generation was comparable to the cleared control microcatheter device.
Ease of use testing	To verify the compatibility of the EMBOTRAP device with the range of microcatheters including PROWLER SELECT PLUS Microcatheter.	The EMBOTRAP device was successfully delivered through PROWLER SELECT PLUS Microcatheter.
Short-length and full-length re-sheathing force testing	To evaluate re-sheathing force (full and short-length) in the PROWLER SELECT PLUS Microcatheter during simulated use in a full-length anatomical model simulating the tortuosity of the neurovascular system.	The EMBOTRAP device was re-sheathed successfully into PROWLER SELECT PLUS Microcatheter and no damage to PROWLER SELECT PLUS was observed during or after testing.
Full-length delivery force during simulated use testing	To evaluate full length delivery force in the PROWLER SELECT PLUS Microcatheter during simulated use in a full-length anatomical model simulating the tortuosity of the neurovascular system.	The delivery forces recorded are acceptable as EMBOTRAP device was successfully delivered through PROWLER SELECT PLUS Microcatheter, with no damage to the microcatheter or subject devices observed during testing.

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 devices. Substantial equivalence of the subject devices has been established to the predicate devices through the results of bench testing.

CONCLUSIONS

Non-clinical studies demonstrate that the EmboTrap® II and EMBOTRAP™ III Revascularization Devices are substantially equivalent to the predicate devices.