July 30, 2021

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

Re: K211338
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: April 30, 2021
Received: May 3, 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)*
K211338

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 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

K211338

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: July 28th, 2021

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 DEVICES

EmboTrap® II Revascularization Device (K173452)

EMBOTRAP™ III Revascularisation Device (5 x 22 mm and 5 x 37 mm models via K193063)

Solitaire™ Platinum Revascularization Device (K160641)

IV. DEVICE DESCRIPTION

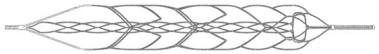
The EMBOTRAP™ III Revascularization Device is composed of a retrievable, self-expanding, Nitinol shaped section at the distal end of a tapered Nitinol shaft. It is designed to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. The EMBOTRAP™ III Revascularization 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 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™ III device in comparison to those of the predicate devices is presented below

Characteristics	Predicate Devices Referenced in this Submission			Proposed SE Device
	EMBOTRAP III (5 x 22 mm and 5 x 37 mm)	**EMBOTRAP II**	**Solitaire™ Platinum**	**EMBOTRAP III (6.5 x 45 mm)**
Manufacturer	**Neuravi Ltd.**	**Neuravi Ltd.**	Covidien/Medtronic	**Same as EMBOTRAP II**
510(k) Number	K193063	K173452	K160641	**N/A**
Classification	Class II (21CFR 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 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 Solitaire Platinum Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel 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 models**
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**
Design/Technological Principles	Retrievable, self-expanding Nitinol shaped section Nitinol guide-wire like shaft			**Same**
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**		**Same as EMBOTRAP II**
	5 x 22 mm  5 x 37 mm 			
Principal Device Materials				
Shaped Section & Shaft Wire	Nitinol	Nitinol	Nitinol	Nitinol
Distal Marker/Coil	Platinum/Tungsten Coil	Platinum/Tungsten Coil	Platinum/Iridium	**Same as EMBOTRAP II**
Proximal Marker/Coil	Platinum/Tungsten Coil	Platinum/Tungsten Coil	Platinum/Iridium	**Same as EMBOTRAP II**
Shaft Coating	Hydrophobic PTFE Coating	Hydrophobic PTFE Coating		**Same as EMBOTRAP II**
Design Characteristics & Technology				
Size(s) Offered (Retriever Diameter × Length)	**5×22mm, 5×37mm,**	**5×21 mm, 5×33 mm**	**6x40 mm**	**6.5x45 mm**
Device Length	**194 cm, 195 cm** (Labeled Overall length)	194 cm, 195 cm (Labeled Overall length)	180 cm (Labeled Push Wire Length)	**196 cm** (Labeled Overall length)
Minimum Microcatheter ID	**0.021"-0.027"**	0.021"	0.027" (6 mm diameter size)	**0.021"-0.027"**
Key Principles of Operation	The device is used in the neurovasculature to restore blood flow in patients experiencing ischemic stroke			**Same**

No. of passes/device IFU	3 / Device & Vessel	3 / Device & Vessel	3 / Device & Vessel	**Same**
Additional Characteristics				
How suppled	Sterile/Single Use	Sterile/Single Use	Sterile/Single Use	**Same**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	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" as recognized by FDA (Recognition Number 2-156) 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", June 16, 2016).

Per ISO 10993-1, the EMBOTRAP™ III device is categorized as an external communicating device with limited exposure, i.e. whose contact with circulating blood is less than 24 hours.

The biocompatibility evaluation included the following tests:

Test	Results	Conclusions
Cytotoxicity Study	The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test. Based on the percentage viability values for the test article extract dilutions, the device is non-cytotoxic.	Device is non-cytotoxic per the Cytotoxicity Studies conducted
ISO Guinea Pig Maximization Sensitization Test	Test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	Device is not considered a sensitizer per the Guinea Pig Maximization Test
ISO Intracutaneous Study in Rabbits	The difference between the test extract overall mean score and the corresponding control overall mean score was 1.0 or less.	Device is not an irritant when injected intracutaneously per the ISO Intracutaneous Study in Rabbits
ISO Systemic Toxicity Study in Mice	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.	Device is non-toxic per the ISO Systemic Toxicity Study in Mice

Test	Results	Conclusions
USP Rabbit Pyrogen Study, Material Mediated	No individual rabbit showed a rise in temperature of ≥ 0.5°C above its baseline temperature and the total maximum temperature rise of all three animals was within acceptable USP limits. The total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.	Device is non-pyrogenic per the Material Mediated Rabbit Pyrogen Study
ASTM Hemolysis	Both the test article in direct contact with blood and the test article extract were non-hemolytic.	Device is non-hemolytic per the ASTM Hemolysis Test
Complement Activation Assay Studies **SC5b-9 Complement Activation Assay Study**	The C3a and SC5b-9 concentrations of the test article samples were acceptable. All test method acceptance criteria were met.	Levels of C3a and SC5b-9 were acceptable.
***In Vivo* Thromboresistance Study in Sheep – Jugular Vein, Acute** **(Thrombogenicity)**	The implantation procedure was routine and there were no difficulties encountered with insertion or placement of the test device. There was no evidence of bleeding or complications during the post-operative implant period. Minimal thrombus formation was associated with the control article and minimal to slight thrombus formation was associated with the test article.	Under the conditions of this study, both test and control articles were considered thromboresistant.

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

Sterilization and Shelf Life:

The EMBOTRAP™ III device is labelled as a single-use, sterile device, with a shelf life of 3 years. 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 SAL of 10^{-6}.

Shelf life studies have been conducted for the EMBOTRAP™ III device and establish that the product and packaging remain functional and sterile for the shelf life period of 3 years.

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

The results of design verification and validation testing conducted on the EMBOTRAP™ III 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 EMBOTRAP™ III is substantially equivalent to the predicate devices.

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

Characteristic/Test	Method	Conclusions
System Dimensions	A range of device dimensions were measured using specified measurement tools to verify that the required dimensional specifications were met for the subject device models.	All required specifications were met. Device dimensions are comparable to legally-marketed mechanical thrombectomy devices. The subject device includes a longer overall length and larger diameter.
Radial Force Testing	Radial force of the subject device models was measured within a range of lumen diameters applicable to the intended vasculature to verify that the device performance specifications have been met.	All required specifications were met. Radial force performance of the subject device is comparable to that of the predicate device.
Outer Cage Recovery	Expansion characteristics of the self-expanding portion of a representative (worst-case) device model were evaluated by measurement post-multiple loading and deployment cycles.	All required specifications were met. Outer cage recovery performance is comparable to that of the predicate.
Durability Testing	Damage was evaluated after delivery and withdrawal of the subject device models beyond the recommended number of passes and re-sheathings recommended in the instructions for use.	All required specifications were met. Durability performance of the subject device is comparable to that of the predicate device.
Full Unit (System) Tensile Testing	The system (full unit) tensile strength of the proximal/distal sections of the device was evaluated post-simulated use.	All required specifications were met. The system tensile strength of the subject device is comparable to that of the predicate device.
Marker Push Out Force	Evaluated the force required to dislodge riveted markers from a representative device model post-simulated use (all marker locations and push-out directions were assessed).	All required specifications were met.
Flexibility & 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.	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.	All required specifications were met. Coating integrity of the subject device is comparable to that of the predicate device.

Torque Durability (Strength)	The effects of torquing the subject device were evaluated using a representative (worst-case) device model post-simulated use with the device positioned as follows (distal end constrained): (a) within the microcatheter in a simulated vessel; and (b) with the shaped section of the device deployed in a simulated vessel following retraction of the microcatheter.	All required specifications were met. Torque durability of the subject device is comparable to that of the predicate device.
Corrosion Resistance	Representative (worst-case) device models were subjected to corrosion testing to determine resistance to corrosion.	All required specifications were met. Corrosion resistance of the subject device is comparable to that of the predicate device.
Tip Flexibility	Tip flexibility was evaluated by measuring the deflection force of the device tip when advanced through a microcatheter past its tip and deflected against contact plates at pre-specified angles.	All required specifications were met. Tip flexibility of the subject device is comparable to that of the predicate device.
Re-sheathing Force	A representative (worst-case) device model was evaluated in a 0.021" microcatheter to determine the force required to re-sheath the device.	All required specifications were met. Re-sheathing force is comparable to those recorded for the predicate devices.
Deliverability 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 0.021" microcatheter.	All required specifications were met.
Radiopacity	The worst-case subject device (least number of radiopaque markers) was evaluated in a skull phantom model using fluoroscopy.	All required specifications were met. Radiopacity of the subject device is equivalent to, or better than, that of the predicate devices tested.
Clot retrieval and performance (Simulated Use/Ease of Use)	Device performance and ease of use attributes (including clot retrieval performance) were evaluated in simulated anatomy for the subject devices in relation to the key steps involved in the clinical procedure.	All required ease of use performance specifications were met. The subject device effectively retrieved clot and restored flow in the test model. Performance of the subject device (including loading, delivery, deployment and retrieval) was comparable to that of the predicate devices tested in an *in vitro* tortuous path anatomical model.

Physician Usability Study	Device performance and ease of use attributes were evaluated in simulated anatomy for the worst-case (largest) subject device model in relation to the key steps involved in the clinical procedure. Performance was compared with the predicate device.	The physician usability study demonstrated that the subject device met user needs. Device performance was comparable to that of the predicate device.
Delivery and re-sheathing force during simulated use (in a clinically-representative, full-length anatomical model)	Delivery and re-sheathing forces were measured during simulated use of a representative (worst-case) device model device in a full-length anatomical model and compared with the forces measured for one or more predicate devices.	Delivery and re-sheathing performance of the subject device are comparable to that of the predicate device.
Kink Resistance – Deployed Shaped Section	Kink resistance of the deployed shaped section of a representative (worst-case) device model was evaluated in a series of bend radii within a range of vessel lumen diameters.	Kink resistance of the deployed shaped section was comparable to that of the predicate device.

***In Vivo* (Animal) Studies:**

Acute and chronic animal studies have been performed to assess the usability, effectiveness and safety of the EMBOTRAP™ III device compared to the predicate devices in the swine model. Acute performance evaluated on Day 0 showed that the usability and performance of the EMBOTRAP™ III device was equivalent to that of the predicate device tested. Histological evaluation performed on treated vessels after 3 and 28 days demonstrated that the local and end organ tissue response was comparable between the EMBOTRAP™ III device and the predicate devices tested.

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 animal testing.

CONCLUSIONS

Non-clinical studies demonstrate that the EMBOTRAP™ III Revascularization Device is substantially equivalent to the predicate devices.