May 21, 2021

Neurescue Aps
℅ H. Semih Oktay
President
CardioMed Device Consultants, LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K210358
Trade/Device Name: Neurescue device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN, DQY, DQO
Dated: April 23, 2021
Received: April 23, 2021

Dear H. Semih Oktay:

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,

for Carmen Johnson, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K210358

Device Name
Neurescue Device

Indications for Use *(Describe)*
The Neurescue device is intended for temporary occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following section is being provided in accordance with 21 CRF 807.92 and contains the 510(k) summary for the NEURESCUE device:

Applicant name and contact information

Name: Neurescue Aps
Address: Købmagergade 53, 2., 1150, Copenhagen, Denmark
Official contact: Habib Frost, M.D.
Contact Telephone: +45 53 53 67 60

Date Prepared: May 15, 2021

Device name and classification

Trade name: NEURESCUE® device
Common name: Occlusion balloon catheter
Classification name: Vascular clamp
Device classification: Class II, 870.4450, 870.1250, 870.1200
Product code: MJN, DQY, DQO

Predicate device

The NEURESCUE device is claimed to be substantially equivalent to the Prytime™ ER-REBOA™ Catheter (K170411).

Device description

The NEURESCUE device is a large vessel occlusion catheter comprised of two main components: The NEURESCUE Catheter and the NEURESCUE Assistant.

The Catheter is an occlusion balloon catheter and the Assistant is a hub for interfacing with the operation of the Catheter. During normal use the device can be operated automatically. Alternatively, the device can be operated manually.

For manual use the interface consists of two Luer lock ports for:

- Manual inflation and deflation of the balloon with saline
- Flushing of the arterial FLUSH port with saline

Inflation and deflation of the balloon can be accomplished by an automatic filling and deflation function (automatic operation with a peristaltic pump) or manually.

Whether the filling is performed manually or automatically, the user is informed of the pressure at the tip of the Catheter. The device has a built-in alarms system.

Intended Use

The NEURESCUE device is intended for temporary occlusion of large vessels and blood pressure monitoring.

Comparison of Technological Characteristics

The NEURESCUE device is identical to the predicate device in terms of intended use and similar in basic characteristics, including:

- A large vessel occlusion balloon
- A hub with Luer lock access to the balloon
- Pressure monitoring capabilities

The NEURESCUE device has the following primary differences from the predicate device:

- Built-in an automatic inflation and deflation function

- Built-in alarms system

Performance bench and *in vivo* testing were performed to support the safety and effectiveness of these differences. The results of these tests demonstrate that the NEURESCUE device has been designed for and tested to conform to its intended use.

Performance Testing
The following *in vitro* tests were performed to demonstrate that the NEURESCUE device meets applicable design and performance requirements and is therefore equivalent to the predicate device:

Summary of *in vitro* testing

Test name / area	Summary
Performance Testing – Bench	Below are listed specific performance testing carried out:
Catheter Dimensional	Dimensional aspects of the Catheter verified, as lumen size, balloon leg distance, peel away cover tube diameters, tip sensor opening dimensions, tip size, catheter effective length and balloon length and diameter.
Radiopacity	Testing with real users with human cadavers that the catheter is visible on fluoroscopy.
Tensile strength	Tensile strength of all adhesive bonds and catheter tip is verified.
Compliance, rated bust volume and freedom from Fragmentation	Test of balloon inflation to burst while observing dimensions and failure mode.
Balloon Fatigue	Repeated use (inflation, deflation and insertion) carried out to verify balloon and catheter mechanical endurance.
Flexibility and kink resistance	Flexibility and kink resistance of the catheter verified.
Torque Strength	Catheter twisted multiple turns to verify torque strength.
Preparation, Deployment and Retraction	Repeated simulated use of catheter testing performed under clinically relevant environment.
Minimum/Maximum vessel occlusion diameter	Verification of status of occlusion for maximum and minimum vessel sizes.
Balloon Regulation	The ability of the system to control the balloon pressure accurately is verified.
Inflation and deflation time	Manual and automated inflation and deflation time is verified.
1-hour occlusion test	Verification that the device is able to sustain a clinically relevant occlusion over 1 hour.
Pressure sensor accuracy	Accuracy of the pressure sensors are carried out, throughout a temperature range taking hysteresis behavior into account.
Systolic and diastolic pressure accuracy	The ability of the device to calculate and show the systolic and diastolic pressure is verified.
Branch vessel indicator alarm	The alarm mechanism to identify inflation of the balloon in a branch vessel to the aorta is verified.
Occlusion time alarm	The alarm mechanism of timing and notifying the user of excessive duration of occlusion is verified.
Pressure relief system	The device incorporates mechanical means of preventing excessive balloon pressure, which is verified.
Battery life time	Testing of the battery operating time for the device is carried out.
Peel-away cover testing	The properties of the peel-away tube covering the balloon is verified.
Free Fall	The device and the device box are tested for free fall (drop test).
Interface integrity testing	Verification of the integrity of the connection interface between the Assistant and the Catheter.
Introducer sheath compatibility	Testing to verify compatibility with the recommended introducer sheaths.
Software Testing	All software requirements and risk control measures implemented in software are tested and verified.
Software unit testing	Part of the release process of every software part, both during development and release, is a full set of software unit test. Included is static code analysis, function testing of units and code coverage tests.
Software system testing	An extensive set of tests are performed verifying aspects of the device where software and hardware are acting together. Everything from pump performance to catheter pairing.
Software validation	Software developed according to IEC 62304 and FDA guidance on “General Principles of Software Validation”. The software is validated.

Electromagnetic Compatibility & Electrical Safety	Electrical safety testing (primarily) according to ANSI AAMI ES60601-1:2005 tested and verified. Electromagnetic compatibility according to IEC 60601-1-2:2014 verified.
Electromagnetic Compatibility	Tested for EMC according to IEC 60601-1-2:2014.
Electromagnetic immunity	Tested for immunity according to IEC 60601-1-2:2014.
Defibrillation	Compliance according to ANSI AAMI ES60601-1:2005 concluded and verified.
Electrostatic discharge	Tested for ESD according to ANSI AAMI ES60601-1:2005 and IEC 60601-1-2:2014.
Packaging, sterilization and shelf life and biocompatibility	Testing to verify performance with respect to biocompatibility, accelerated aging, the packaging's ability to protect the device through the lifetime of the device and the adequacy of the sterilization processes.
Packaging, sterilization	Packaging testing for (accelerated) aged products and products put through transit testing carried out. Validation of the two sterilization methods used for two different parts performed (EO and E-BEAM). This includes bioburden and endotoxin testing.
Accelerated aging	Accelerated aging and relevant testing to verify performance has been carried out. The test suite is a repeat of the relevant tests also carried out prior to aging; cover tube removal, vessel occlusion, pressure sensor accuracy, inflation and deflation time test, flexibility and kink, torque strength, balloon volume vs diameter to burst, battery lifetime, pump regulation, water container burst test and water container diffusion.
Marker bands integrity and depth markers legibility testing	Verification of marker bands integrity and verification of the legibility of the position and depth markers on aged products.
Biocompatibility testing	Biocompatibility testing carried out for Cytotoxicity, Irritation / intracutaneous reactivity, Sensitization, Acute systemic toxicity, Material-mediated pyrogenicity and Hemocompatibility.

The following *in vivo* tests were performed to demonstrate that the NEURESCUE device meets applicable design and performance requirements and is therefore substantially equivalent to the predicate device:

- A GLP Study to Evaluate the Performance of the NEURESCUE Catheter in the Aorta of an Acute Naïve Porcine Model

Conclusion

The NEURESCUE device is substantially equivalent to the identified predicate device.