January 15, 2021

Vesalio
Sigi Caron
Regulatory and Clinical Consultant
Biologics and Medical Device Consulting Group
PO Box 7605
Mammoth Lakes, California 93546

Re: K201085
Trade/Device Name: NeVa™ PV Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: December 15, 2020
Received: December 17, 2020

Dear Sigi Caron:

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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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)*
K201085

Device Name
NeVa PV Thrombectomy Device

Indications for Use *(Describe)*

The NeVa™ PV Thrombectomy Device is indicated for:

- The non-surgical removal of emboli and thrombi from peripheral blood vessels.
- Temporary use in peripheral vessel occlusion.
- Use with aspiration and with the injection or infusion of contrast media and other fluids.

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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1. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(K) NUMBER	K201085
DATE PREPARED	January 13, 2021
APPLICANT	Vesalio Gustavo R. Prado, PhD gprado@vesalio.com 3200 West End Ave, Ste 500 Nashville, TN 37203
OFFICIAL CORRESPONDENT	Sigi Caron, MBA RAC Biologics and Medical Device Consulting Group 4260 Paul Sweet Rd. Santa Cruz, CA 95065 Tel: (310) 614-3120 Fax: (888) 295-1535 sigi@BioMDG.com
TRADE NAME	NeVa™ PV Thrombectomy Device
COMMON NAME	Embolectomy Catheter
DEVICE CLASSIFICATION	Product Codes: QEW – Catheter, Embolectomy (21 CFR §870.5150) KRA – Catheter, Continuous Flush (21 CFR) §870.1210) Class: II
PREDICATE DEVICE	ReVive™ PV Thrombectomy Device (K132281)
REFERENCE DEVICE	Trevo Provue Thrombus Retriever (K122478) Solitaire Platinum Revascularization Device (K160641)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The NeVa™ PV Thrombectomy Device is a sterile, single-use thrombectomy device designed to for use in the peripheral vasculature to restore blood flow via non-surgical removal of emboli and thrombi from peripheral vessels in the vasculature. The NeVa™ PV device consists of a self-expanding nitinol basket attached to a core pusher wire that can be delivered through a micro catheter, deployed across a clot, and then removed with the clot to enable revascularization of the occluded vessel. To aid in fluoroscopic visualization, radiopaque markers are positioned at the distal end, proximal end, and along the nitinol basket of the NeVa™ PV device. A flexible

atraumatic soft tip attached to the distal end of the nitinol basket is radiopaque for enhanced fluoroscopic visualization.

The NeVa™ PV device is provided sterile and is intended for single patient use. The device is not intended to be re-sterilized or re-used. No accessories are provided with the NeVa™ PV device. The device is intended to be used in conjunction with the appropriately sized microcatheter as indicated in the proposed Instructions for Use.

INDICATIONS FOR USE:

The NeVa™ PV Thrombectomy Device is indicated for:

- The non-surgical removal of emboli and thrombi from peripheral blood vessels.
- Temporary use in peripheral vessel occlusion.
- Use with aspiration and with the injection or infusion of contrast media and other fluids.

SUBSTANTIALLY EQUIVALENT TO:

The NeVa™ PV Thrombectomy Device is substantially equivalent in intended use and technological features to the ReVive™ PV Thrombectomy Device (K132281).

SUMMARY OF TECHNOLOGICAL CHARACTERISTIC SIMILARITIES / DIFFERENCES:

The NeVa™ PV Thrombectomy Device and the predicate ReVive™ PV Thrombectomy Device are both sterile, single-use thrombectomy devices intended to restore blood flow via non-surgical removal of emboli and thrombi from peripheral vessels. Both the NeVa™ PV and the ReVive™ PV use a self-expanding nitinol basket to capture emboli and thrombotic material in occluded vessels. Both devices have a soft distal tip, integrated radiopaque markers for fluoroscopic visualization during the procedure, and are constructed of equivalent materials. Both devices are introduced by being loaded in an insertion sheath that is then delivered via a compatible microcatheter to the target vessel location for deployment.

The only notable difference between two the devices is that the NeVa™ PV Thrombectomy Device uses a different cell design (net pattern) in the nitinol basket structure. The NeVa PV incorporates a proprietary drop zone pattern to optimize capture of emboli and thrombotic material. The diameter of the basket remains similar in size, and the method of clot capture (entrapment) remains the same. There are no other technological differences between the two devices.

The NeVa™ PV device will also be offered in a range of configurations and sizes in order to provide more options to the interventionalist and to accommodate clot removal in different anatomical locations..

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The NeVa™ PV Thrombectomy Device is substantially equivalent to the ReVive™ PV with respect to indications for use (intended use) and technical characteristics. The following table compares the features of the proposed NeVa™ PV device to its predicate.

Element	New Device: NeVa™ PV Thrombectomy Device	Primary Predicate: ReVive™ PV Thrombectomy Device
510(k) Number	K201085	K132281
Indications for Use	• The non-surgical removal of emboli and thrombi from peripheral blood vessels. • Temporary use in peripheral vessel occlusion. • Use with aspiration and with the injection or infusion of contrast media and other fluids.	• The non-surgical removal of emboli and thrombi from peripheral blood vessels. • Temporary use in peripheral vessel/graft occlusion. • Use with aspiration and with the injection or infusion of contrast media and other fluids. • The non-surgical removal of thrombi from synthetic grafts.
Design Features		
Use of basket to capture clot?	Yes	Yes
Vessel Diameter Range	2.0 – 6.0 mm	1.5 – 5.0 mm
Basket Type	Self-Expanding Closed Cell Basket	Self-Expanding Closed Cell Basket
Basket Material	Nitinol	Nitinol
Basket - Maximum Available Diameters	4.0, 4.5, and 6.0 mm	4.5 mm
Basket – Working Lengths	22 – 46 mm	22 - 28 mm
Basket Radiopaque Markers	Yes	Yes
Soft Distal Tip	Yes	Yes
Distal Tip Length	5 mm	6 mm
Distal /Proximal Radiopaque Markers	Yes	Yes
Radiopaque Marker Material	Platinum	Platinum
Core Pusher Wire	Yes	Yes
Pusher Wire Material	Nitinol	Nitinol
Compatible Microcatheter Sizes	0.021”, 0.027”	0.027”

Element	New Device: NeVa™ PV Thrombectomy Device	Primary Predicate: ReVive™ PV Thrombectomy Device
Loaded into Introducer Sheath?	Yes	Yes
Provided Sterile?	Yes	Yes
Single Use?	Yes	Yes

PERFORMANCE STANDARDS:

No performance standards have been established by the Agency to date that apply to this device.

SUMMARY OF NONCLINICAL TESTING:

Comprehensive design verification and validation testing was performed on the NeVa™ PV Thrombectomy Device. Results from bench and animal testing demonstrated substantial equivalence to the predicate. Testing performed included a combination of the following:

- Physical and Dimensional Inspection
- Tensile Strength
- Af Temperature
- Radial Forces
- Torque Strength / Torsion
- Delivery / Retrieval Forces
- Multiple Re-sheathing Durability
- Navigation/Steerability
- Flexibility/Kink Resistance
- Tip Deflection
- Radiopacity
- Corrosion Resistance
- Clot Retrieval Testing
- Physician Usability Testing
- Biocompatibility Testing (ISO 10993-1)
- Sterilization Validation (ISO 11137-1)
- Packaging Validation (ISO 11607-1 and -2)
- GLP Animal Study

Overall, testing confirms that the NeVa™ PV Thrombectomy Device can be used according to its intended use and in an equivalent manner to the predicate device.

CONCLUSION:

Based on the above information, Vesalio believes that the substantial equivalence of the NeVa™ PV Thrombectomy Device to the ReVive™ PV Thrombectomy Device has been demonstrated.