December 22, 2020

Vascular Medcure, INC.
C/O Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street
Suite 2300
Philadelphia, Pennsylvania 19103

Re: K203476
Trade/Device Name: CAPERE Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: November 25, 2020
Received: November 25, 2020

Dear Janice Hogan:

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 on last page

510(k) Number *(if known)*

K203476

Device Name

CAPERE® Thrombectomy System

Indications for Use *(Describe)*

The CAPERE® Thrombectomy System is indicated for:

- Non-surgical removal of soft emboli and thrombi from blood vessels.
- Injection, infusion and/or aspiration of contrast media and other fluids into blood vessel.

The CAPERE® Thrombectomy System is intended only for use in the peripheral vasculature and is not intended for use in the pulmonary arteries.

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 Food and Drug Administration
Office of Chief Information Officer
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
K203476

Vascular Medcure, Inc.'s CAPERE® Thrombectomy System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Jeffrey P. DuMontelle

Vascular Medcure, Inc.

1500 S. Sunkist Street, Suite H

Anaheim, CA 92806

Office: 657-549-5175

Cell: 714-915-0886

Date Prepared: November 25, 2020

Name of Device

CAPERE® Thrombectomy System

Common or Usual Name

Embolectomy Catheter

Classification

21 CFR 870.5150, Class II, product code QEW, KRA

Predicate Devices

CAPERE® Thrombectomy System (K200314) (Primary predicate device)

CAPERE® Thrombectomy System (K201216) (Reference device)

Intended Use / Indications for Use

The CAPERE® Thrombectomy System is indicated for:

- Non-surgical removal of soft emboli and thrombi from blood vessels.
- Injection, infusion and/or aspiration of contrast media and other fluids into blood vessel.

The CAPERE® Thrombectomy System is intended only for use in the peripheral vasculature and is not intended for use in the pulmonary arteries.

Device Description

The CAPERE® Thrombectomy System primarily consists of a Delivery Catheter and Guide Catheter. The CAPERE® Thrombectomy System is delivered percutaneously via transfemoral or jugular venous access. Once delivered, the System's fine mesh nitinol wire basket is used to capture and mechanically remove emboli and thrombi. The CAPERE® System does not use aspiration to pull out the thrombus but does have a side port in the funnel catheter that allows aspiration or injection of saline or fluids if needed.

Technological Characteristics

The CAPERE® Thrombectomy System has the same technological characteristics as its predicate device CAPERE Thrombectomy Catheter (K200314). Both CAPERE® Thrombectomy Systems have either the same components or substantially equivalent components. Each device system includes a guide catheter, delivery catheter, and a mechanism for capturing/removing the soft emboli or thrombi. The CAPERE® Thrombectomy System utilizes either the identical basket as the predicate (18mm basket) or a smaller basket (14mm basket) to capture the soft emboli or thrombi. The CAPERE® Delivery Catheter basket also includes a tether to help maintain the basket perpendicularity during retraction. In addition, the CAPERE® Thrombectomy System and the predicate both use a 0.035" guidewire during the procedure.

The CAPERE® System includes a Guide Catheter and a Delivery Catheter. In the same manner as the previously cleared device, the Guide Catheter and Delivery Catheter are advanced to the therapy site. The funnel of the Guide Catheter is unsheathed, and the Delivery Catheter is then advanced passed the obstruction. A nitinol basket connected to the Delivery Catheter is deployed by retracting the outer sheath of the catheter.

To capture the soft emboli or thrombi ("clot"), the deployed basket is retracted while simultaneously being extended to surround and capture the length of the clot. The Delivery Catheter and clot-load is then retracted into the funnel of the Guide Catheter where the clot is captured and can be removed.

The basket design in the CAPERE® Thrombectomy Systems is the same (nitinol,11.4cm length) as the basket design in the predicate. The only difference between the baskets of the two systems is the addition of the suture support to the basket to aid in maintaining basket perpendicularity during basket retraction and the addition of the smaller 14mm basket.

Therefore, the subject CAPERE® Thrombectomy System has the same technological characteristics as its predicate.

Performance Data

The following nonclinical performance testing has been conducted, using the established test methods used in the cleared predicate device, to support the substantial equivalence of the CAPERE® Thrombectomy System to its predicate device. In all instances, the CAPERE® Thrombectomy System functioned as intended under the previously established test methods.

- Functional bench testing was conducted (including demonstrated compliance with relevant standards such as ISO 10555-1 and ISO 594-2) on the compression resistance and bond joints affected by the change in diameter of the CAPERE® Thrombectomy System with respect to the predicate and demonstrated that the CAPERE® Thrombectomy System maintained the predicate characteristics. Specifically,
    - The force to retract the basket into the funnel catheter was evaluated in accordance with the same simulated-use test method used to clear the predicate and the CAPERE® was determined to meet the same retraction force requirements as the predicate.

- The ability of the CAPERE® to capture and remove clot was evaluated in the accordance with the same simulated-use test method used to clear the predicate and the CAPERE® was determined to completely capture and remove the simulated clot and therefore maintains the characteristics of the predicate.

- The materials and packaging are unchanged from the predicate therefore the biocompatibility, sterilization, and packaging characteristics of the predicate were maintained.

Substantial Equivalence

The CAPERE® Thrombectomy System has the same intended use and indications for use, technological characteristics, and principles of operation as its predicate devices. Nonclinical testing, including functional testing and simulated use testing demonstrated that the minor differences between the device and predicate (i.e., addition of suture support and additional 14mm basket configuration) do not raise new types of safety or effectiveness questions. Thus, the CAPERE® Thrombectomy System is substantially equivalent to the predicate devices.

Conclusion

Vascular Medcure's CAPERE® is an Embolectomy Catheter, Class II device that has been evaluated in nonclinical testing in accordance with FDA's recognized standards and pre-established acceptance criteria. Testing demonstrated that the device performs as intended. The CAPERE® is substantially equivalent to its predicate device.