June 11, 2018

KP Medcure, Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K180722
Trade/Device Name: CAPERE Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 2, 2018
Received: April 2, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180722

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.

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510(k) SUMMARY

KP Medcure, Inc.'s CAPERE™ Thrombectomy System

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

Samuel Shaolian
KP Medcure, Inc.
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Date Prepared: March 19, 2018

Name of Device

CAPERE™ Thrombectomy System

Common or Usual Name

Embolectomy Catheter

Classification

21 CFR 870.5150, Class II, product code DXE

Predicate Devices

Infusion Aspiration Catheter System (K143563) (Primary Predicate)

MSD Embolectomy Basket (K991093) (Reference Predicate)

Fogarty Venous Thrombectomy Catheter (510(k)-Unknown) (Reference Predicate)

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 consists of a 12Fr Delivery Catheter and a 20Fr Guide Catheter. The 12Fr Delivery Catheter consists of a nitinol basket that comes in two different sizes (10 mm and 18 mm). The 20Fr Guide Catheter consists of an inner and outer guide and an inner and outer introducer.

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 extract thrombus but does have a side port in the guide catheter that allows aspiration or injection of saline or fluids if needed.

Technological Characteristics

The CAPERE™ Thrombectomy System has similar technological characteristics as its predicate devices. Both the CAPERE™ Thrombectomy System and the primary predicate device have similar components. Each device system includes a 20F guide catheter, dilator catheter, 12F catheter, and a mechanism for capturing/removing the soft emboli or thrombi. Both the CAPERE™ and its primary predicate use a 20F guide catheter with similar inner diameters (5.8 mm for the CAPERE™ versus 5.9 mm for the primary predicate). In addition, both systems use commercially available 0.035" guidewires during the procedure.

The CAPERE™ System includes a guide catheter and a Delivery Catheter. The Delivery Catheter is advanced distal to the obstruction, and a nitinol basket connected to the catheter is deployed by retracting the outer sheath of the catheter. The Delivery Catheter is inserted into the Guide Catheter, which includes a funnel at its distal tip to cap and contain the embolus within the basket. Comparatively, the primary predicate system similarly includes a dilator catheter (which fits inside the guide catheter), and an embolus disrupt/delivery catheter (Infusion Wireform Catheter). The internal Wireform Catheter has expanding wireform disks attached to its distal end. The Infusion Wireform Catheter is advanced distal to the obstruction, and wireform disks are deployed by retracting the delivery catheter. The predicate disrupts/removes the obstructing material by the withdrawal of the Infusion Wireform Catheter into the guide catheter, similar to the CAPERE™ System.

The basket designs in both the CAPERE™ Thrombectomy System and the reference predicate, MSD Embolectomy Basket (K991093) have similar technological characteristics. Similar to the mechanism of the CAPERE™, the MSD Embolectomy Basket's nitinol wire frame component is retracted into the sheath by operation of the handle, which first closes the mouth of the sack, and then configures it for retraction with the frame into the sheath.

Therefore, the subject CAPERE™ Thrombectomy System has very similar technological characteristics as its predicates.

Performance Data

The following nonclinical performance testing has been conducted to support the substantial equivalence of the CAPERE™ Thrombectomy System to its predicate devices. In all instances, the CAPERE™ Thrombectomy System functioned as intended.

- Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993.
- Package integrity and accelerated aging studies were completed per ISO 11607-1, ASTM D4332-14, ASTM D4169-16, ASTM F88/F88M-15, ASTM F2096-11, and ASTM 1980-16.

- Functional bench testing was conducted (including demonstrated compliance with relevant standards such as ISO 10555-1 and ISO 80369 (formerly ISO 594-1)).
    - Testing included visual inspection, dimensional testing, guidewire compatibility, catheter trackability, delivery/guide catheter radio-detectability, delivery/guide catheter kink resistance, luer compatibility, force to deploy basket testing, force to recapture basket in guide catheter testing, leak test for all appropriate bonds/joints, tensile testing, corrosion resistance, flexibility testing, funnel deployment force testing, funnel recapture force testing, torsion testing, and basket resistance to rupture testing, packaging validation (ISO 10555-1: 2014, ISO 594-2, ISO 11607-1).
- Simulated Use Testing was completed to demonstrate that simulated clot can be retrieved under simulated conditions without filter rupture, catheter damage, or other adverse device effect.
- *In vivo* testing in an animal model was performed to evaluate and establish the substantial equivalence of the CAPERE™ Thrombectomy System to the predicate device. The purpose of the study was to compare acute and chronic overall performance and handling, regional, and downstream vascular safety, clinical pathologic, and overall in-life clinical outcomes compared to the predicate device.

Substantial Equivalence

The CAPERE™ Thrombectomy System has the same intended use and very similar indications for use, technological characteristics, and principles of operation as its predicate devices. Nonclinical testing, including functional testing, simulated use testing, and in vivo testing in an animal model, demonstrated that the minor differences in technology do not raise new types of safety or effectiveness questions. Thus, the CAPERE™ Thrombectomy System is substantially equivalent to the predicate devices.

Conclusion

KP 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 devices.