December 21, 2018

ICHOR Vascular, Inc.
℅ Ms. Angela Mallery
Principal Product Development Strategist, Regulatory
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re: K182167
Trade/Device Name: The ICHOR Panacea Vascular Embolectomy Catheter System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 30, 2018
Received: December 3, 2018

Dear Ms. Mallery:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Eleni Whatley
Date: 2018.12.21 09:21:13 -05'00'

For

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
The ICHOR Panacea Vascular Embolectomy Catheter System

Indications for Use (Describe)
The Panacea embolectomy system is indicated for the non-surgical removal of emboli and thrombi from blood vessels. The device is intended for the peripheral vasculature, and is not intended for use in the coronary or neurovasculature.

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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TRADITIONAL 510(K) SUMMARY

K182167: The ICHOR Panacea Vascular Embolectomy Catheter System

Submitter: ICHOR Vascular Inc.
2865 N Reynolds Rd
Suite 220A
Toledo OH 43615

Contact Person: Angela Mallery
400 Highway 169 South, Suite 500,
Minneapolis, MN 55426
Phone: (763) 287-3830
amallery@namsa.com

Summary Preparation Date: December 20, 2018
Device Name: The ICHOR Panacea Vascular Embolectomy Catheter System

Device Classification: Embolectomy Catheter
DXE
21 CFR 870.5150

Intended Use: The Panacea embolectomy system is indicated for the non-surgical removal of emboli and thrombi from blood vessels. The device is intended for the peripheral vasculature, and is not intended for use in the coronary or neurovasculature.

Contraindications: None

Device Description: The fundamental mechanism of action is temporary vessel occlusion combined with mechanical balloon embolectomy and aspiration through a guide catheter. The sheath provides vessel access. The occlusion balloon catheter is intended for temporary vessel occlusion and the guide catheter functions to remove emboli and thrombi. The devices are provided sterile, non-pyrogenic, and intended for single use only.

Predicate Device: MegaVac (K171493)

Reference Devices: Fogarty Occlusion Catheter (K152762)
Penumbra Embolectomy Aspiration System (K160533)
The device is substantially equivalent to the predicate devices regarding its similar intended use, design, function, materials and sterilization method. In accordance with risk analysis and according to international standards, verification testing was conducted.

The subject and predicate/reference devices are considered equivalent, the device has the equivalent intended use as the predicate; The Panacea and the predicate both have the ability to capture clot in a Nitinol basket, and have the option to aspirate with a syringe; The design of the subject device and the predicate devices are substantially equivalent with only minor differences to the type of material, sizes, and dimensions; While the predicate does not use a balloon as an occlusive element (using a Nitinol basket instead) the reference device (Fogarty) does use an occlusive balloon; The Panacea and the predicate both are intended to treat the same disease and are used in the same patient population.

ICHOR asserts when comparing the Panacea and the predicate; the differences in technology do not raise different questions of safety and effectiveness and that the device is substantially equivalent to a legally marketed device,” respectively

The device and the predicate both occlude the vessel in order to capture clot, the device uses a Pellethane balloon and a Nitinol basket whereas the predicate uses a coated Nitinol basket and a Nitinol element to achieve the same outcome.

While the predicate does not use a balloon as an occlusive element (using a Nitinol basket instead) the reference device (Fogarty) does use an occlusive balloon.

There are minor differences in dimensions between the Panacea and MegaVac Systems, these can be attributed to the MegaVac systems have a broader indication for use.
Summary of Testing:
Device evaluation consisted of in vitro testing and supports the substantial equivalence to the predicate device. All data met the acceptance criteria and fell within pre-determined product specifications and industry standard requirements. The following is a list of tests that were performed:

- RX Balloon Catheter Embolectomy Sheath testing
  - Balloon performance and dimensions
  - Dimensions
  - Leak testing
  - Tensile testing
  - Marker Band Fluoro Opacity
  - Balloon inflation and deflation time
  - Balloon durability
- Biocompatibility
- Sterilization
- Packaging
- Transportation and Shelf life
- Seal and package integrity testing
- Animal testing
- Guide Catheter testing
  - Dimensions
  - Funnel durability
  - Funnel radial force
  - Marker band fluoro opacity
  - Kink resistance
  - Tensile strength
- Dilator testing
  - Dimensions
  - Kink resistance
  - Tensile strength
- System testing
  - Full system testing
  - Torque strength testing
  - Clot capture

Conclusion: As described in this 510(k) Summary, the device is substantially equivalent to the predicate based on a comparison of intended uses and the results of in-vitro testing.