September 5, 2023

Ichor
Angela Mallery
Regulatory
1900 NW 25th St.
Boca Raton, Florida 33431

Re: K230743
Trade/Device Name: ICHOR 14F Embolectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: August 3, 2023
Received: August 3, 2023

Dear Angela 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/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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.09.05 15:45:12 -04'00'

For

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)*
K230743

Device Name
The ICHOR 14F Embolectomy System

Indications for Use *(Describe)*
The ICHOR 14F Embolectomy System is indicated for the non-surgical removal of emboli and thrombi from venous blood vessels. The System 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K230743

Date prepared	August 31, 2023
Name	ICHOR 1900 NW 25th St. Boca Raton FL 33431 United States
Contact person	Angela Mallery amallery@namsa.com 763-287-3830
Name of Device	ICHOR 14F Embolectomy System
Common name	Embolectomy catheter
Regulation name	Peripheral Mechanical Thrombectomy With Aspiration
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II

Predicate and Reference Devices

	Predicate #	Predicate Trade Name	Product Code
Predicate device	K182531	The ClotTriever Thrombectomy System	QEW
Reference device	K182167	ICHOR Panacea	QEW
	K171493	MegaVac Mechanical Thrombectomy System	QEW
	K152762	Fogarty Occlusion Catheter	MJN

Device Description

The ICHOR 14F Embolectomy System is indicated for the non-surgical removal of emboli and thrombi from blood vessels. The System is intended for the peripheral venous vasculature (nominal size 8-14mm).

The System is composed of three catheters: (1) Introducer Sheath, (2) Guide Catheter, and (3) Balloon Catheter and accessories.

- The outermost catheter is the Introducer Sheath, which travels to the occlusion site over the dilator. The Introducer Sheath is placed proximal to the occlusion and anchored into place by inflating the occluding balloon located at the distal tip. The balloon on the Introducer Sheath also serves to occlude flow.
- The Guide Catheter, composed of the Basket Catheter telescoped within the Guide Catheter Sheath, is passed through the Introducer Sheath. When in place, the Guide Catheter Sheath, which serves as the capturing sleeve, is retracted proximally allowing a nitinol basket to expand within the vasculature proximal to the occlusion.
- The Balloon Catheter is passed through the Guide Catheter and extended past the occlusion. The treatment balloon is inflated distal to the occlusion, and the Balloon Catheter is pulled proximally towards the basket until the occlusion is contained inside the basket. If desired the Guide Catheter can introduce aspiration to apply negative pressure to guide embolic material into the basket.
- The accessories include a dilator, flush adapter, two 3cc syringes, a Tuohy Borst, and four extension lines with one-way stopcocks.

Indications for Use

The ICHOR 14F Embolectomy System is indicated for the non-surgical removal of emboli and thrombi from venous blood vessels. The System is intended for the peripheral vasculature and is not intended for use in the coronary or neurovasculature.

Comparison of Technological Characteristics with the Predicate Device

Minor differences in the indication for use are acceptable and do not raise new questions of safety or effectiveness; the predicate had additional indications for injections and infusion of fluid; the lack of this indication does not raise additional questions.

Minor technological differences exist between the predicate and subject device; both devices are designed to capture clot with a basket and have the option to aspirate via a syringe; minor differences in dimensions have been verified and validated through bench and animal testing and the testing confirms these do not raise new questions of safety and effectiveness than the predicate device.

The reference devices were included to confirm/demonstrate the technology has similar situations FDA has encountered in the past; the reference devices are used in the identical anatomical location for the same purpose as the subject device. The ICHOR Panacea 7F uses the same basket/balloon configuration; the MegaVac also uses a Nitinol Basket for removal of clot, the Fogarty devices use a balloon for the movement of clot. The MegaVac and Fogarty devices were the used to support the ICHOR Panacea 7F device.

Although the predicate and subject devices have different technological characteristics, all leveraged and performed design verification and validation tests confirm that these differences do not raise any new or different questions of safety or effectiveness.

Summary of substantial equivalence

Substantial Equivalence Executive Summary		
	ICHOR 14F	**ClotTriever K182531**
Indications for Use	The ICHOR 14F Embolectomy System is indicated for the non-surgical removal of emboli and thrombi from venous blood vessels. The device is intended for the peripheral vasculature, and is not intended for use in the coronary or neurovasculature.	The ClotTriever Thrombectomy System consists of the ClotTriever Catheter and ClotTriever Sheath. The ClotTriever Thrombectomy System is indicated for: The non-surgical removal of soft thrombi and emboli from blood vessels. Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature
Nitinol Funnel (max)	18mm	14mm
Treatment Balloon Material/Size	Pebax Diameter: 14mm / Length 15mm	No balloon, Nitinol coring element
Usable Catheter Lengths	Balloon catheter: 100cm Guide catheter: 55cm Introducer sheath: 15cm	105cm deployed 74cm usable
Biocompatibility	Tested to 10993-1	Tested to 10993-1
Sterilization	EO	EO
Packaging	Tyvek Packaging	Tyvek Packaging
Aspiration Mechanism	Syringe	Syringe

Non-Clinical Testing Performed

Biocompatibility Testing:

- Acute Systemic Toxicity
- Cytotoxicity
- Hemocompatibility
  - complement activation
  - direct and indirect hemolysis
  - in vivo thrombogenicity (leveraged from GLP animal study
- Irritation
- Material-Mediated Pyrogenicity
- Sensitization

Bench Testing:

- Accelerated Aging Testing Protocol
- Balloon characterization Testing
  - balloon fatigue
  - balloon inflation/deflation time
  - balloon compliance
- Basket Durability
- Basket Radial Force Testing
- Bend Radius Testing
- Hub Pressurization Testing
- Package Integrity and Bubble Leak
- Radiopacity Testing
- Seal Peel Testing
- Simulated Use Testing
- Tensile Testing
- Torque Strength Testing
- Visual and Dimensional

Sterilization: The device is ethylene oxide sterilized and met the requirements for ethylene oxide and ethylene chlorohydrin residuals per ISO 10993- 7:2008/Amd1:2019; and met the requirements for bacterial endotoxin per AAMI/ANSI ST72:2019.

Animal Study: A GLP study was conducted, comparing the ICHOR 14F Embolectomy System to a comparator device at an acute timepoint. Adverse Events, clinical observations, clinical pathology excursions, gross pathological, and histomorphological finding were evaluated.

Conclusion	The ICHOR 14F Embolectomy System is substantially equivalent to the predicate device.