July 18, 2024

ICHOR Vascular, Inc. (ICHOR)
% Brandon Woll
Principal Strategy Consultant, Regulatory and R&D
Namsa
400 Highway 169 South
Suite 500
Minneapolis, Minnesota 55426

Re: K233917
Trade/Device Name: ICHOR 7F Embolectomy System (ICH-7F)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: December 12, 2023
Received: December 12, 2023

Dear Brandon Woll:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.07.18 10:43:21 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233917

Device Name
ICHOR 7F Embolectomy System (ICH-7F)

Indications for Use *(Describe)*
The ICHOR 7F 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.

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.

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510(k) Summary

In accordance with the regulatory requirements of 21 CFR Part 807.92, the 510(k) Summary for the ICHOR 7F Embolectomy System is provided below.

Assigned 510(k) Number: K233917

A. Applicant Information

Applicant Name:	ICHOR
Contact Person:	Timothy Blair
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Correspondent Name:	NAMSA
Contact:	Adam Saltman
Address:	400 Highway 169 South, Suite 500 Minneapolis, MN 55426
Telephone:	(347) 860-1872
E-mail:	asaltman@namsa.com

B. Date Prepared

17 July 2024

C. Device Name

Device Trade Name:	ICHOR 7F Embolectomy System (ICH-7F)
Common Name:	Embolectomy Catheter
Device Classification:	Peripheral Mechanical Thrombectomy with Aspiration
Regulation:	870.5150
Product Code:	QEW

D. Predicate Device Names

Predicate Device:	ICHOR Panacea Vascular Embolectomy Catheter System
Predicate #:	K182167
Predicate Product Code:	QEW

E. Device Description Summary

The ICHOR 7F Embolectomy System is indicated for the non-surgical removal of emboli and thrombi from blood vessels. The System is intended for the peripheral vasculature (nominal size 4-10mm).

The ICHOR 7F consists of four components: the Introducer Sheath, the Dilator, the Guide Catheter, and the Balloon Catheter.

- 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 two 1 cc syringes, two Tuohy Borst with extension lines, two three-way stopcocks, two one-way stopcocks, and one stylet.

F. Intended Use/Indications for Use

The ICHOR 7F 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.

G. Technological Comparison

Minor technological differences exist between the predicate and subject device; minor differences have been verified and validated through bench testing and the testing confirms these do not raise different questions of safety and effectiveness than the predicate device.

Feature	**Subject Device – ICHOR 7F Embolectomy System (ICH-7F) -** K233917	**Predicate Device – The ICHOR Panacea Vascular Embolectomy Catheter System -** K182167	**Comparison**
Indication for Use	The ICHOR 7F 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.	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.	**Same**
Regulation Number	21 CFR 870.5150	21 CFR 870.5150	**Same**
Regulatory Class	Class II	Class II	**Same**
Product Code	QEW	QEW	**Same**
Nitinol Funnel (max)	10.5 mm	10.5 mm	**Same**
Treatment Balloon Material/Size	Low durometer Pebax Diameter: 10 mm	Pellethane 10 mm – 12 mm	**Different** Change to balloon material and diameter
Usable Catheter Lengths	Balloon catheter: 145 cm Guide catheter: 90 cm Introducer Sheath 50.0 cm	150 cm	**Different** Changes to catheter length, Guide Catheter, and Introducer Sheath Length
Biocompatibility	Tested to 10993-1	Tested to 10993-1	**Same**
Sterilization	EO	EO	**Same**
Packaging	Tyvek Packaging	Tyvek Packaging	**Same**
Aspiration Mechanism	Syringe	Syringe	**Same**

H. Non-Clinical Test Summary

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:

- Performance Testing
  - Balloon Compliance Testing
  - Balloon Fatigue Testing
  - Balloon Inflation Testing
  - Radial Force Testing
  - Thrombus Evacuation Testing
  - Bend Radius Testing
  - Leak Testing
  - Radiopacity Testing
  - Simulated Use Testing
  - Tensile Testing
  - Torque Testing
  - Dimension Evaluation

- Biocompatibility Evaluations
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Acute Systemic Toxicity
  - Pyrogenicity
  - Hemocompatibility
- Sterilization
- Packaging
- Transportation

I. Conclusion

Non-clinical testing supports substantial equivalence of the subject device to the predicate device.