February 9, 2024

Inari Medical, Inc.
Kaitlyn Weinkauf
Sr. Regulatory Affairs Specialist
6001 Oak Canyon
Suite 100
Irvine, California 92618

Re: K234034
Trade/Device Name: VenaCore™ Thrombectomy Catheter (46-101)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: December 20, 2023
Received: December 20, 2023

Dear Kaitlyn Weinkauf:

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: 2024.02.09 11:57:56 -05'00'

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.

Submission Number *(if known)*

K234034

Device Name

VenaCore™ Thrombectomy Catheter (46-101)

Indications for Use *(Describe)*

The VenaCore Thrombectomy Catheter is indicated for:

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

The VenaCore Thrombectomy Catheter is intended for use in the peripheral vasculature.

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

Date prepared	February 9, 2024
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Trade name	VenaCore™ Thrombectomy Catheter (46-101)
Common name	Embolectomy Catheter
Regulation name	Embolectomy Catheter
Classification number	21 CFR 870.5150
Primary product code	QEW
Secondary product code	KRA
Regulatory class	II
Predicate device	Inari Medical, RevCore™ Thrombectomy Catheter (K223609)
Description	The VenaCore Thrombectomy Catheter is a single-use, sterile, over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The VenaCore Thrombectomy Catheter is designed to remove thrombi and emboli in the peripheral vasculature. The VenaCore Thrombectomy Catheter consists of a distal laser-cut nitinol coring element, three coaxial catheter shafts (inner, middle, and outer), and a handle with a diameter control knob and a lever. The proximal handle controls the expansion and collapse of the coring element via the handle knob and lever. The outer shaft constrains the coring element prior to deployment. To aid in fluoroscopic visualization, the distal tip is radiopaque, and a radiopaque tip is located on the outer catheter to identify the distal end of the outer catheter.
Indications for Use	The VenaCore Thrombectomy Catheter is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels. The VenaCore Thrombectomy Catheter is intended for use in the peripheral vasculature.

Summary of substantial equivalence

A tabular comparison of the predicate and subject devices is provided below:

	Subject Device VenaCore Thrombectomy Catheter	***Predicate Device*** RevCore Thrombectomy Catheter
510(k) Number	TBD	K223609
Manufacturer	Inari Medical, Inc.	Inari Medical, Inc.
Regulation	21 CFR 870.5150 Embolectomy catheter	21 CFR 870.5150 Embolectomy catheter
Product Code	QEW, KRA	QEW
Intended Use	The VenaCore Thrombectomy Catheter is intended for use in the peripheral vasculature for the removal of thrombus and emboli from blood vessels and the infusion of fluids into blood vessels.	The RevCore Thrombectomy Catheter is intended for use in the peripheral vasculature for the removal of thrombus and emboli from blood vessels and the infusion of fluids into blood vessels.
Indications for Use	The VenaCore Thrombectomy Catheter is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels. The VenaCore Thrombectomy Catheter is intended for use in the peripheral vasculature.	The RevCore Thrombectomy Catheter is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels. The RevCore Thrombectomy Catheter is intended for use in the peripheral vasculature.
Device Description	The VenaCore Thrombectomy Catheter is a single-use, sterile, over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The VenaCore Thrombectomy Catheter is designed to remove thrombi and emboli in the peripheral vasculature. The VenaCore Thrombectomy Catheter consists of a distal laser-cut nitinol coring element, three coaxial catheter shafts (inner, middle, and outer), and a handle with a diameter control knob and a lever. The proximal handle controls the expansion and collapse of the coring element via the handle knob and lever. The outer shaft constrains the coring element prior to deployment. To aid in fluoroscopic visualization,	The RevCore Thrombectomy Catheter is a single-use, sterile, over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature, and within venous stents. The RevCore Thrombectomy Catheter consists of a distal laser-cut nitinol coring element, three coaxial catheter shafts (inner, middle, and outer), and a handle with a diameter control knob. The proximal handle controls the expansion and collapse of the coring element via the handle knob. The middle and inner shaft constrains the coring element prior to deployment. To aid in fluoroscopic visualization, the distal tip is radiopaque, and a radiopaque tip is located on the outer catheter to

	the distal tip is radiopaque, and a radiopaque tip is located on the outer catheter to identify the distal end of the outer catheter.	identify the distal end of the outer catheter.
Principles of Operation	The coring element is composed of self-expanding nitinol and the diameter is manually controlled by a knob in the handle. The coring element is retracted through the vessel to engage and remove thrombus and emboli. The device and captured clot are removed from the vessel through the introducer sheath.	The coring element is composed of self-expanding nitinol and the diameter is manually controlled by a knob in the handle. The coring element is retracted through the vessel to engage and remove thrombus and emboli. The device and captured clot are removed from the vessel through the introducer sheath.
Catheter OD	12 Fr	12 Fr
Effective Length	80 cm	80 cm
Coring Element Description	The VenaCore Thrombectomy Catheter element contains 6 nitinol struts that pair off and connect in the center to compose a series of diamond cell patterns.	The RevCore Thrombectomy Catheter element contains 6 nitinol struts that have a single connection point on the distal and proximal end. The element struts themselves are cut in such a way that it retains some features from the original laser cut tubing, which is referred to as the "wave."
Coring Element Actuation Mechanism	Knob and lever active diameter control. This is achieved by the relative movement of the inner and mid shaft. The inner shaft and mid shaft work together to axially compress or elongate the element, which in turn expands/contracts the element to the desired treatment diameter.	Knob active diameter control. This is achieved by the relative movement of the inner and mid shaft. The inner shaft and mid shaft work together to axially compress or elongate the element, which in turn expands/contracts the element to the desired treatment diameter.
Element Material	Nitinol laser cut hypotube	Nitinol laser cut hypotube
Inner Catheter Material	Nitinol hypotube	Nitinol hypotube
Middle Catheter Material	Nitinol Hypotube 316L Stainless Steel 18-8 Stainless Steel	Pebax 35D, Cool Grey 8C 304V Stainless Steel 316 Stainless Steel
Outer Catheter Material	Pebax 72D, Cool Grey 4C Pebax 72D, Violet C 316 stainless steel 304V stainless steel	Pebax 63D, Cool Grey 4C Pebax 63D, Violet C Pebax 55D, Violet C PTFE Liner 90% Platinum / 10% Iridium Split Marker Band 304V stainless steel
Target Vessel	Peripheral vessels 6-16 mm	Peripheral vessels 6-20 mm
Sterilization	SAL 10^{-6}, EtO	SAL 10^{-6}, EtO

Shelf-life	6 months	24 months
Guidewire compatibility	0.035”	0.035”
Single use	Yes	Yes

Summary of substantial equivalence

Biocompatibility

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility (Hemolysis, Complement Activation, Thromboresistance, Platelet and Leukocyte Count, and Partial Thromboplastin Time)

The results demonstrate that the subject device meets biological safety requirements per ISO 10993-1:2018.

Sterilization

The subject device, including its accessories, is sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6} using a validated sterilization process in accordance with the principles of ISO 11135:2014/Amd 1:2018 and AAMI TIR28:2016.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the VenaCore Thrombectomy Catheter to the predicate device. These tests included:

Design Verification Testing

- Pouch Seal Visual Inspection
- Bubble Leak
- Dye Penetration
- Packaging Usability Evaluation for Aseptic Presentation
- Pouch Peel and Seal Strength
- Label Integrity
- Visual and Dimensional Inspection
- Deairing/Flushing
- Guidewire Compatibility
- Knob Torque Testing
- Handle Lever Testing
- VenaCore Element Deployment Force from Delivery Catheter
- VenaCore Element Retraction Force into Delivery Catheter
- VenaCore Distal Catheter Kink Radius
- VenaCore Element Durability Inspection
- VenaCore Delivery Catheter Durability Inspection

- Insertion of VenaCore Catheter through Sheath
- Advancement Force of VenaCore Catheter through Sheath
- Retraction Force of VenaCore Catheter through Sheath
- Leakage Test, Sheath
- Vacuum Test, Sheath
- Air Leakage, Sheath
- Leakage Test, VenaCore Catheter
- Tensile Testing, VenaCore Catheter
- Tensile Testing, Delivery Catheter
- Torque Testing, VenaCore Catheter
- Rotation Testing, VenaCore Delivery Catheter
- Corrosion Testing
- Particulate Matter Testing
- ISO 80369-7 and ISO 80369-20 Luer Testing – Proximal Luer and Middle Catheter Luer
- Clot Removal Efficacy (Characterization Only)
- *In Vivo* Functional Testing/Radiopacity Verification

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications.

Clinical testing was not required for the determination of substantial equivalence.

Conclusion

The VenaCore Thrombectomy Catheter has the same intended use/indications for use and principles of operation as the predicate. Non-clinical performance data show that the different technological characteristics between the devices do not raise any new or different questions of safety or effectiveness and support the VenaCore Thrombectomy Catheter's substantial equivalence to the predicate device.