March 14, 2023

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

Re: K223609
Trade/Device Name: RevCore™ Thrombectomy Catheter.
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: February 23, 2023
Received: February 24, 2023

Dear Suzanne Moreno:

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.03.14 09:29:30 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223609

Device Name
RevCoreTM Thrombectomy Catheter

Indications for Use *(Describe)*
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 a blood vessel.

The RevCore Thrombectomy Catheter is intended for use in the peripheral vasculature system

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 K223609
RevCore™ Thrombectomy Catheter

The following "510(k) Summary" of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

1.0 Submitter Information [21 CFR 807.92(a) (1)]

Submitter:	Inari Medical, Inc.
Address:	6001 Oak Canyon, Suite 100 Irvine, CA 92618 USA
Establishment Registration #:	3020347218
Contact:	Suzanne Moreno
Title:	Sr. Regulatory Affairs Specialist
Telephone:	(949) 694-9459
e-mail	Suzanne.Moreno@inarimedical.com

Date Prepared: January 04, 2023

2.0 Device Information [21 CFR 807.92 (a) (2)]

Device/Trade Name:	RevCore™ Thrombectomy Catheter
Device Classification:	Class II
Primary Product Code:	QEW
Regulation:	21 CFR 870.5150
Regulation Name:	Embolectomy catheter
Common Name:	Embolectomy catheter
Classification Panel:	74-Cardiovascular

3.0 Predicate, and Reference Device Information [21 CFR 807.92(a) (3)]

Predicate Device	510(k) No.	Decision Date	510(k) Holder
ClotTriever BOLD Catheter	K212632	10/18/2021	Inari Medical, Inc.
Reference Device	**510(k) No.**	**Decision Date**	**510(k) Holder**
FlowTriever Retrieval/Aspiration System	K201541	12/04/2020	Inari Medical, Inc.

4.0 Device Description [21 CFR 807.92(a) (4)]

The RevCore Thrombectomy Catheter is a single-use, sterile medical device designed for use in the peripheral vasculature. The RevCore Thrombectomy Catheter comprises reinforced polymeric and metal coaxial shafts terminating in an expandable coring element. Two ports are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the RevCore Thrombectomy Catheter distal tip and coring element are radiopaque. The RevCore Thrombectomy Catheter consists of a distal laser-cut nitinol coring element, catheter shafts, and a handle, providing wall-to-wall contact, allowing the engagement and retrieval of clot from blood vessels and from implanted venous stents. The catheter shafts introduce the nitinol coring element percutaneously. The handle allows the physician to retract and turn the nitinol coring element to engage clot, as well as control the diameter of the nitinol coring element with a knob.

5.0 Intended Use/Indications for use of device and Indications for Use [21 CFR 807.92(a) (5)]

Indications for Use

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 a blood vessel.

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

6.0 Summary of Substantial Equivalence [21 CFR 807.92 (a) (6)]

The RevCore Thrombectomy Catheter is similar/same in indications for use, fundamental design, principles of operation, materials, labeling/packaging, and sterilization compared to the Inari owned devices, the predicate, the ClotTriever BOLD Catheter (K212632), and the reference device, the FlowTriever Retrieval/Aspiration System (K201541).

The comparisons are listed in the table below:

	Subject	Predicate Device	Reference Device
Device	**RevCore Thrombectomy Catheter**	**ClotTriever BOLD Catheter**	**FlowTriever Retrieval/Aspiration System**
510(k) Number	**K223609**	**K212632**	**K201541**
Manufacturer	Inari Medical	Inari Medical	Inari Medical
Product code	QEW	QEW	QEW KRA
Device Class	Class II	Class II	Class II
Indications for Use Statements	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 a blood vessel. The RevCore Thrombectomy Catheter is intended for use in the peripheral vasculature.	The ClotTriever BOLD 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 a blood vessel. The ClotTriever BOLD Catheter is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).	The FlowTriever 2 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 a blood vessel. The FlowTriever 2 Catheter is intended for use in the peripheral vasculature.

	Subject	Predicate Device	Reference Device
Device	**RevCore Thrombectomy Catheter**	**ClotTriever BOLD Catheter**	**FlowTriever Retrieval/Aspiration System**
510(k) Number	**K223609**	**K212632**	**K201541**
Device Description	The RevCore Catheter is a single-use, sterile, minimally invasive medical device designed for use in the peripheral vasculature. The RevCore Catheter is comprised of reinforced polymeric and metallic coaxial shafts terminating in an expandable coring element. Two ports are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the RevCore Catheter distal tip is radiopaque.	The ClotTriever BOLD Catheter is a single-use, sterile, minimally invasive medical device designed for use in the peripheral vasculature. The ClotTriever BOLD Catheter is comprised of reinforced polymeric and metallic coaxial shafts terminating in an expandable coring element and thrombus collection bag. Three ports are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the ClotTriever BOLD Catheter distal tip is radiopaque.	The FlowTriever System is a single-use, sterile, minimally invasive medical device designed for use in the peripheral vasculature. The FlowTriever Catheters are comprised of reinforced polymeric and metallic coaxial shafts terminating in an expandable coring element. One port is provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the FlowTriever Catheter distal tip is radiopaque.
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 can then be 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 plunger in the handle. The coring element is retracted through the vessel to engage and remove thrombus and emboli. The device and captured clot can then be removed from the vessel through the introducer sheath.	The disk(s) are composed of self-expanding nitinol which are deployed by manually retracting the outer Delivery Catheter. The coring element is retracted through the vessel to engage and remove thrombus and emboli. The device and captured clot can then be removed from the vessel through the introducer sheath.

	Subject	Predicate Device	Reference Device
Device	**RevCore Thrombectomy Catheter**	**ClotTriever BOLD Catheter**	**FlowTriever Retrieval/Aspiration System**
510(k) Number	**K223609**	**K212632**	**K201541**
Power Source	Manually operated	Manually operated	Manually operated
Sterile	SAL 10-6, EO	SAL 10^{-6}, EO	SAL 10^{-6}, EO
Number of disks / coring elements	Model 44-101: 1	Model 42-102: 1	Model 11-102: 1 Model 10-104: 3
Recommended vessel size treatment range	Model 44-101: 6mm - 20mm	Model 42-102 6mm - 16mm	Model 11-102 6mm – 16mm Model 10-104 19mm – 25mm
Maximum Disk / Coring Element Size	Model 44-101: 24.0mm	Model 42-102: 16.0mm	Model 11-102: 17.0mm Model 10-104: 27.9mm
Disk / coring element material	Nitinol	Nitinol	Nitinol
Delivery Catheter shaft materials	Pebax 6333 SA01 MED, Pebax 5533 SA01 MED, 304V stainless steel, PTFE Liner	Pebax 6333 SA01 MED, Pebax 5533 SA01 MED, 304V stainless steel, PTFE Liner	Pebax 7233 SA01 MED, Pebax 4033 SA01 MED, 304V stainless steel, PTFE Liner
Tip Materials	Pebax 7233 SA01 MED, 45% Tungsten	Pebax 7233 SA01 MED, 70% Tungsten	Pebax 7233 SA01 MED, 70% Tungsten
Delivery Catheter OD	3.9 mm	3.9 mm	3.8 mm
Delivery Catheter length	80 cm	80 cm	120 cm
Guidewire compatibility	.035”	.035”	.035”

7.0 Performance Testing [21 CFR 807.92(b)(1)]

In accordance with the Design Failure Modes and Effects Analysis, verification and validation tests were identified to support the substantial equivalence of the RevCore Thrombectomy Catheter to the predicate device, the ClotTriever BOLD Catheter (K212632), and the reference device, the FlowTriever Retrieval/Aspiration System (K201541).

7.1 Performance Testing

The following tests were performed for the RevCore Thrombectomy Catheter:

Packaging Tests & Inspections

- Pouch Seal Inspection
- Pouch Dye Penetration
- Pouch Bubble Leak
- Aseptic Presentation

Dimensions & Key Characteristics

- Visual and Dimensional Inspections
  - RevCore Catheter
  - RevCore Coring Element
  - RevCore Delivery Catheter
- Guidewire Compatibility

Performance & Functional Evaluation

- Deairing/Flushing Testing
- Knob Torque Testing
- Deployment and Retraction Force through the Delivery Catheter
- Coring Element Retraction into Delivery Catheter Inspection
- Distal Catheter Kink Radius Testing
- Coring Element Durability Inspection (Post-Simulated Use)
- Insertion through Sheath
- Retraction Force through Sheath
- Sheath Inspection (Post-Simulated Use)
- Leakage Testing, Sheath (Post-Simulated Use)
- Vacuum Testing, Sheath (Post-Simulated Use)
- Leakage Testing, RevCore Catheter (Post-Simulated Use)
- Delivery Catheter Durability Inspection (Post-Simulated Use)
- Simulated Use Tracking and Tensile Testing (Post-Simulated Use)
- Simulated Use Tracking and Torque Testing (Post-Simulated Use)
- Corrosion Testing
- Particulate Matter Determination
- Luer Testing
- Safety Testing in Stent Model

Characterization Tests

- Radial Force Characterization
- Efficacy Testing (Clot & Stent Model)
- SEM of Stents/RevCore Coring Elements Post-Treatment

Leveraged Tests

- Pouch Seal Strength
- Simulated Use Tracking and Rotation Testing
- Delivery Catheter Radiopacity

Pre-Clinical Study

A GLP Animal Study was successfully performed to evaluate the safety and performance of the RevCore Thrombectomy Catheter. The GLP animal testing met the predetermined acceptance criteria.

7.2 Biocompatibility

Biocompatibility testing for the RevCore Thrombectomy Catheter was completed in accordance with ISO 10993-1 including:

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

7.3 Sterilization

The subject device is sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6}. The subject device has been adopted into a validated sterilization process in accordance with the principles of ISO 11135:2014 (Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices, and AAMI TIR 28:2016 (Product adoption and process equivalence for ethylene oxide sterilization) without deviations.

7.4 Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject predicate, and reference devices per their intended uses, no clinical studies were deemed necessary to support this submission.

All non-clinical test results demonstrated that acceptance criteria were met; therefore, the device conforms to established product specifications.

8.0 Conclusions Safety and Effectiveness SW [21 CFR 807.92(b) (3)]

The subject device has successfully passed all acceptance criteria for non-clinical performance testing and biocompatibility, demonstrating that the subject device is substantially equivalent to the legally marketed predicate ClotTriever BOLD Catheter (K212632).