August 4, 2022

Inari Medical
Ellen Nguyen
Regulatory Affairs Specialist
6001 Oak Canyon, Suite 100
Irvine, California 92618

Re: K220887
Trade/Device Name: Mini-ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW
Dated: June 24, 2022
Received: June 27, 2022

Dear Ellen Nguyen:

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 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)*
K220887

Device Name
Mini-ClotTriever Thrombectomy System

Indications for Use *(Describe)*
The Mini-ClotTriever Thrombectomy System is indicated for:

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

The Mini-ClotTriever Thrombectomy System is intended for use in the peripheral vasculature.

The Mini-ClotTriever Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date prepared	August 3, 2022
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Trade name	Mini-ClotTriever Thrombectomy System
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II
Predicate device	Inari ClotTriever Thrombectomy System (K210689)
Reference device	Merit Medical Prelude Short Sheath Introducer (K082063) Rex Medical Cleaner Rotational Thrombectomy System (K091029) Vesalio NeVa PV Thrombectomy Device (K201085)
Description	The Mini-ClotTriever ("MCT") Thrombectomy System is a single-use, over-the-wire, catheter-based system for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The system is comprised of two main components packaged separately: • Mini-ClotTriever Sheath (8 Fr) • Mini-ClotTriever Catheter (8 Fr) The MCT Sheath is placed in the target vessel, and, after its funnel is expanded, the MCT Catheter is inserted through the sheath and advanced past the thrombus. The MCT Catheter coring element is deployed to engage the clot and retracted into the MCT Sheath to capture the targeted thrombus. Additional clot may be removed by aspiration through the sheath with a syringe (not provided). After the procedure is complete, the MCT Catheter and MCT Sheath are removed from the patient.
Indications for Use	The Mini-ClotTriever Thrombectomy System is indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Mini-ClotTriever Thrombectomy System is intended for use in the peripheral vasculature.

The Mini-ClotTriever Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment.

Device Modifications

The proposed modifications to the ClotTriever Thrombectomy System include material, design, and dimensional changes to the sheath and catheter.

The purpose for these modifications is to introduce the Mini-ClotTriever Thrombectomy System, a ClotTriever Thrombectomy System variant.

Comparison of Technological Characteristics with the Predicate Device

The subject device and predicate device have a similar design and materials of construction. The modifications do not change the intended use or the principles of operation from the predicate device. The ClotTriever and Mini-ClotTriever are both tracked over a pre-placed compatible guidewire. The Mini-ClotTriever Catheter performs mechanical thrombectomy (coring and entrapping clot and withdrawing through the sheath) following the same method as the predicate ClotTriever Catheter.

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

The Mini-ClotTriever System and ClotTriever System have the same indications for use: both are indicated for the non-surgical removal of emboli and thrombi from blood vessels and the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. Both are intended for use in the peripheral vasculature, but unlike the predicate device, the Mini-ClotTriever is not indicated for use in treating deep vein thrombosis.

A tabular comparison of specific technological characteristics between the predicate and subject device is provided below:

Feature	**Mini-ClotTriever Thrombectomy System (K220887)**	**ClotTriever Thrombectomy System Predicate (K210689)**
Manufacturer	Inari Medical	Inari Medical
Product code	QEW	QEW
Intended use/Indications for use	The Mini-ClotTriever Thrombectomy System is indicated for: • The non-surgical removal of emboli and thrombi 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 indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

Feature	Mini-ClotTriever Thrombectomy System (K220887)	ClotTriever Thrombectomy System Predicate (K210689)
	The Mini-ClotTriever Thrombectomy System is intended for use in the peripheral vasculature. The Mini-ClotTriever Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment.	The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature *including deep vein thrombosis (DVT)*.
Device description	The Mini-ClotTriever Thrombectomy System consists of the Mini-ClotTriever Sheath and the Mini-ClotTriever Catheter. The Mini-ClotTriever Sheath is comprised of reinforced polymeric coaxial sheath shafts equipped with a self-expanding distal mesh funnel, a flush/aspiration port, and a proximal hemostatic valve. The Mini-ClotTriever Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable nitinol coring element/collection bag (basket). Other accessories provided include a pre-dilator and dilator.	The ClotTriever Thrombectomy System consists of the ClotTriever Sheaths and the ClotTriever Catheter. The ClotTriever Sheaths are comprised of a reinforced polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port, and a proximal hemostatic valve. The ClotTriever Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Other accessories provided include a pre-dilator, dilator, the funnel loading tool, and a Large Bore 60 cc syringe.
Principles of operation	The Mini-ClotTriever Catheter is advanced into the vessel beyond the clot. The self-expanding nitinol coring element is deployed. The expanded coring element cores, separates, and entraps thrombus from the vessel as it is being drawn to the funnel opening of the Mini-ClotTriever Sheath. The coring element is pulled through the Mini-ClotTriever Sheath with the entrapped clot. A syringe (not provided) can be used for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.	The ClotTriever Catheter is advanced into the vessel and beyond the clot. The self-expanding braided nitinol wire net is deployed. The expanded net cores, separates, and entraps thrombus from the vessel as it is being drawn to the funnel opening of the ClotTriever Sheath. The net is collapsed and pulled into and through the ClotTriever Sheath with the entrapped clot. A 60 cc syringe is provided for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.

Feature	Mini-ClotTriever Thrombectomy System (K220887)	ClotTriever Thrombectomy System Predicate (K210689)
Target vessel	Peripheral vessels 4-10 mm	Peripheral vessels 6-16 mm
Contraindicated vessels	< 4 mm	< 6 mm
Guidewire compatibility	0.035”	0.035”
Shelf-life	6 months	2 years
Sterilization	EtO	EtO
Single-use	Yes	Yes
Mini-ClotTriever Sheath		
Sheath dimensions	Outer shaft: 0.154” OD/0.137” ID Inner shaft: 0.137” OD/0.110” ID Length: 6 cm	16 Fr: 0.248” OD/0.215” ID 13 Fr: 0.210” OD/0.182” ID Length: 15 cm
Shaft material	Pebax 55D, ProPell PTFE Liner Stainless steel coil Radiopaque marker band	Pebax 72D and 63D, ProPell PTFE Liner Stainless steel coil Radiopaque marker band
Outer shaft material	Pebax 40D and 25D, ProPell PTFE Liner	N/A
Hemostasis valve	8 Fr Garrote valve Rotating swivel hub with side port	13 or 16 Fr Garrote valve Rotating swivel hub with side port
Handle	Slide actuator enclosed within handle housings	N/A
Braided funnel	OD: 10 mm Length: 0.70” Nitinol #2 Wire	OD: 14 mm Length: 0.90” Nitinol #2 Wire
Side port	Tygon tubing 1-way stopcock with female Luer connector	Tygon tubing Flushing stopcock and quick-connect
Dilator	OD: 0.110” Working length: 17.8 cm Tipped LDPE/HDPE extrusion Dilator cap Proximal flush port	OD: 0.206” (16 Fr) or 0.178” (13 Fr) Working length: 26 cm Pebax 55D and 72D, ProPell Slide actuator enclosed within handle housings Proximal flush port Braid cover/tip
Pre-Dilator	OD: 0.13” (10 Fr) Polypropylene, HDPE Length: 10.2 cm	OD: 0.53” (16 Fr) or 0.64” (19 Fr) LDPE/HDPE

Feature	Mini-ClotTriever Thrombectomy System (K220887)	ClotTriever Thrombectomy System Predicate (K210689)
		Length: 27 cm
Mini-ClotTriever Catheter		
Delivery catheter (outer)	OD: 0.111” PTFE Liner SS304V Braid Radiopaque marker band	OD: 0.14” PTFE Liner SS304V Braid Radiopaque marker band
	63D Pebax Jacket 63D Pebax Fluoro-safe marker band Proximal hub with Tuohy Borst hemostasis Y-valve and 1-way stopcock	63D Pebax Jacket 63D Pebax Fluoro-safe marker band Proximal hub with hemostasis valve and side port with 1-way stopcock
Middle catheter	Braided polyimide Radiopaque marker band	Braided polyimide Radiopaque marker band 72D Pebax over-mold
Inner catheter	Braided polyimide Radiopaque 55D Pebax tip with ProPell	Braided polyimide Radiopaque 72D Pebax, tungsten tip 72D Pebax over-mold
Length	65 cm	80 cm
Coring element	Laser-cut nitinol OD: 18 mm Length: 88 mm No collection bag	Laser-cut nitinol OD: 16 mm Length: 42 mm Collection bag length: 190 mm
Proximal handle	No	Yes

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 passing results demonstrate that the subject device and accessories meet biological safety requirements per ISO 10993-1.

Sterilization

The subject device, including its accessories, 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/Amd 1:2018 (*Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E, Single batch release*) and AAMI TIR 28:2016 (*Product adoption and process equivalence for ethylene oxide sterilization*) without deviations.

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 Mini-ClotTriever. These tests included:

- Pouch Seal Visual Inspection and Dye Penetration
- Visual & Dimensional Inspection – Delivery Catheter
- Visual & Dimensional Inspection – Element Catheter
- Visual & Dimensional Inspection - Sheath
- Visual & Dimensional Inspection – Dilator
- Guidewire Compatibility
- Coring Element Comparative Radial Force Testing
- Sheath Funnel Comparative Radial Force Testing
- Catheter Leak Testing
- Sheath Leak Testing
- Simulated Use, Pre-dilator
- Simulated Use, Sheath/Dilator
- Simulated Use, Catheter
- Simulated Use, System
- Retraction with Clot Analog
- Post Pre-Conditioning Leak Testing
- Sheath Shaft Side Loading
- Tensile Testing Sheath
- Tensile Testing Catheter
- Corrosion Testing

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

Neither animal testing nor clinical testing were required for the determination of substantial equivalence.

Conclusion

The Mini-ClotTriever Thrombectomy System has the same intended use and principles of operation as the predicate. Performance data shows that the different technological characteristics between the devices do not raise any new or different questions of safety or effectiveness. Non-clinical bench testing supports the Mini-ClotTriever's substantial equivalence to the predicate device.