March 17, 2023

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

Re: K223613
Trade/Device Name: InThrill Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: February 14, 2023
Received: February 14, 2023

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.03.17 13:13:36 -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)*
K223613

Device Name
InThrill Thrombectomy System

Indications for Use *(Describe)*
The InThrill Thrombectomy System is indicated for:

- The non-surgical removal of thrombi and emboli from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft.

The InThrill Thrombectomy System is intended for use in the peripheral vasculature.

The InThrill 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.

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510(K) SUMMARY

Date prepared	March 16, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Trade name	InThrill Thrombectomy System
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Secondary product code	KRA
Regulatory class	II
Predicate device(s)	Capture Vascular, MegaVac Mechanical Thrombectomy System (K171493) Hotspur Technologies, Inc., PTA-Plus PTA Balloon Catheter (K100842) Inari Medical, Mini-ClotTriever Thrombectomy System (K220887)
Reference device(s)	Intramed Laboratories, Inc., Graft Thrombectomy Instruments (K942457) Rex Medical, Cleaner Rotational Thrombectomy System (K141617)
Description	The InThrill™ Thrombectomy System is a single-use, sterile medical device designed to remove thrombi and emboli from the peripheral vasculature. The InThrill™ Thrombectomy System consists of the InThrill Sheath ("Sheath") and the InThrill Thrombectomy Catheter ("Catheter"), each packaged separately. The Sheath is an introducer sheath with a distal self-expanding funnel, proximal aspiration port, and proximal hub. A Dilator is provided to aid insertion and positioning of the Sheath. Radiopaque markers aid Sheath positioning under fluoroscopic visualization. The Sheath and Dilator tips are radiopaque, and there is a radiopaque marker band at the proximal end of the Sheath funnel.
Indications for Use	The InThrill Thrombectomy System is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft.

The InThrill Thrombectomy System is intended for use in the peripheral vasculature.

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

Summary of substantial equivalence

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

	Subject Device InThrill Thrombectomy System	***Primary Predicate*** MegaVac Mechanical Thrombectomy System	***Predicate*** PTA-Plus PTA Balloon Cather 5mm X 4cm, PTA-Plus PTA Balloon Catheter 6mm X 4cm	***Predicate*** Mini-ClotTriever Thrombectomy System
K Number	K223613	K171493	K100842	K220887
Manufacturer	Inari Medical, Inc.	Capture Vascular, Inc.	Hotspur Technologies, Inc.	Inari Medical, Inc.
Regulations	21 CFR 870.5150 Embolectomy catheter	21 CFR 870.5150 Embolectomy catheter	21 CFR 870.5150 Embolectomy catheter 21 CFR 870.1250 Percutaneous catheter	21 CFR 870.5150 Embolectomy catheter
Product Code	• QEW • KRA	• QEW • QEX • DXE	• DXE • LIT	• QEW
Indications for Use	The InThrill Thrombectomy System is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft. The InThrill Thrombectomy System is intended for use in the peripheral vasculature.	The MegaVac Mechanical Thrombectomy System is indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • The non-surgical removal of thrombi from synthetic grafts. • Use in temporary blood vessel/graft occlusion. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft • Catheter placement over a guidewire	The PTA-Plus PTA Balloon Catheter is indicated for use within synthetic arteriovenous dialysis fistulae to remove embolic material (thrombus/debris) and dilate stenosis for treatment of obstructive lesions.	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.

	The InThrill Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment.			
Device Description	The InThrill Thrombectomy System is a single-use, over-the-wire, catheter-based system for the minimally invasive treatment of thromboemboli (including organized thrombus and adherent thrombotic material) in the peripheral vasculature, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts. The system comprises two main components packaged separately: • InThrill Sheath (8 Fr) • InThrill Thrombectomy Catheter (8 Fr) The InThrill 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 InThrill Thrombectomy Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable nitinol coring element (basket). Other accessories provided	The MegaVac Mechanical Thrombectomy System is a single-use, over-the-wire, catheter-based system for intravascular mechanical thrombectomy, occlusion, aspiration and embolectomy in the peripheral vasculature, including grafts. The system comprises two main components: • MegaVac Catheter • ThromboWire clot retractor The MegaVac Catheter with SafeSeal technology utilizes a silicone coated nitinol braided funnel that expands to occlude antegrade blood flow proximal to the target work zone creating a static environment in which to perform the intervention, while also centering and securing the catheter tip position within the vessel. The MegaVac catheter's large-mouth funnel and inner diameter allows for strong aspiration while easily being able to pass the ThromboWire and other lesion disruptive or therapeutic devices through it. The	The PTA-Plus PTA Balloon Catheter is designed for de-clotting and treating stenosis in synthetic dialysis fistulae. It is an .035" guide-wire compatible, PTA balloon catheter with a proprietary valve system which allows injection of contrast and an embolectomy coil for mechanical removal of thrombus.	The Mini-ClotTriever 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 comprises two main components packaged separately: • Mini-ClotTriever Sheath (8 Fr) • Mini-ClotTriever Catheter (8 Fr) 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 (basket). Other accessories provided include a pre-dilator and dilator.

	include a pre-dilator and dilator.	ThromboWire consists of a nitinol embolectomy element that when expanded by the proximal actuation handle can serve to gather and pull matter towards and through the MegaVac catheter during aspiration.		
Target Vessel	Peripheral vessels (4-10 mm) that include: • native vessels • arteriovenous fistulae • arteriovenous grafts • synthetic grafts	Peripheral vessels that include: • native vessels • synthetic grafts	Peripheral vessels that include: • arteriovenous fistulae • arteriovenous grafts • synthetic grafts	Peripheral vessels (4-10 mm) that include: • native vessels
Sterility	SAL 10^{-6}, EO	SAL 10^{-6}, EO	SAL 10^{-6}, EO	SAL 10^{-6}, EO
Shelf-life	2 years	Unknown	Unknown	2 years *
Guidewire compatibility	0.035”	Up to 0.044” OD	0.035”	0.035”
Sheath Dimensions	Outer shaft: 0.154” OD/0.137” ID Inner shaft: 0.137” OD/0.110” ID Length: 6 cm	Up to 9 Fr OD Length: up to 300 cm	Unknown	Outer shaft: 0.154” OD/0.137” ID Inner shaft: 0.137” OD/0.110” ID Length: 6 cm
Shaft Materials	Inner: Pebax 55D, ProPell, PTFE Liner, Stainless steel coil, Radiopaque marker band Outer: Pebax 63D, ProPell, PTFE Liner	Unknown	Unknown	Inner: Pebax 55D, ProPell, PTFE Liner, Stainless steel coil, Radiopaque marker band Outer: Pebax 40D and 25D, ProPell, PTFE Liner
Hemostasis Valve	8 Fr Garrote valve Rotating swivel hub with side port	Unknown	Unknown	8 Fr Garrote valve Rotating swivel hub with side port
Handle	Yes; Slide actuator enclosed within handle housings	Yes; Operator controlled – linear actuation	Unknown	Yes; Slide actuator enclosed within handle housings
Braided Funnel	OD: 10 mm Length: 0.70” Braided nitinol funnel	OD: 2-12 mm Silicone coated braided nitinol funnel	Unknown	OD: 10 mm Length: 0.70” Braided nitinol funnel
Side Port	Tygon tubing with Loctite adhesive 1-way stopcock with female Luer connector	Unknown	Unknown	Tygon tubing with Loctite adhesive 1-way stopcock with female Luer connector

Dilator	OD: 0.110” Total length: 8.8” Tipped LDPE/HDPE extrusion Dilator cap Proximal flush port	Unknown	Unknown	OD: 0.110” Total length: 8.3” Tipped LDPE/HDPE extrusion Dilator cap Proximal flush port
Pre-Dilator	OD: 0.13” (10 Fr) Polypropylene, HDPE Length: 10.2 cm	Unknown	Unknown	OD: 0.13” (10 Fr) Polypropylene, HDPE Length: 10.2 cm
Catheter	OD: 0.111” Proximal hub with Tuohy Borst hemostasis Y-valve and 1-way stopcock Materials: Outer: PTFE Liner, SS304V Braid, Radiopaque marker band, 63D Pebax Jacket, 63D Pebax Fluoro-safe marker band Middle: Braided polyimide, Radiopaque marker band, Pebax 72D Inner: Braided polyimide, Radiopaque 55D Pebax tip with ProPell	Nitinol	Unknown	OD: 0.111” Proximal hub with Tuohy Borst hemostasis Y-valve and 1-way stopcock Materials: Outer: PTFE Liner, SS304V Braid, Radiopaque marker band, 63D Pebax Jacket, 63D Pebax Fluoro-safe marker band Middle: Braided polyimide, Radiopaque marker band, Loctite 3942 Inner: Braided polyimide, Radiopaque 55D Pebax tip with ProPell
Length	65 cm	Up to 300 cm	55 cm	65 cm
Coring Element	Laser-cut nitinol OD: 18 mm Length: 88 mm	Woven nitinol OD: 2-9 mm	Unknown	Laser-cut nitinol OD: 18 mm Length: 88 mm

Summary of substantial equivalence

Biocompatibility

The material changes proposed in this submission have no impact on the established biocompatibility of the device. Therefore, the previous passing results demonstrating that the InThrill Thrombectomy System (K220887) and accessories meet biological safety requirements per ISO 10993-1 are still applicable.

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 TIR 28:2016. There have been no changes proposed that would affect device

sterilization; therefore, the previous sterilization process per K220887 remains applicable.

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 InThrill Thrombectomy System to the predicate devices. These tests included:

Performance Tests

- Graft Leak Testing (Pre-Simulated Use)
- In-Graft Simulated Use, InThrill Thrombectomy System
- Graft Leak Testing (Post-Simulated Use)
- Graft Visual Inspection (Post-Simulated Use)
- Radial Force Testing
- Prescale Contact Paper Pressure Testing
- Graft Abrasion Testing
- Comparative Adherent Clot Removal Testing
- Visual Inspection of Vein-to-Graft Anastomosis (Pre-Simulated Use)
- Simulated Use, InThrill Catheter through Vein-to-Graft Anastomosis
- Visual Inspection of Vein-to-Graft Anastomosis (Post-Simulated Use)

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

Pre-Clinical Study

A GLP Animal study was performed, which did not identify any new questions of safety or effectiveness for the InThrill Thrombectomy System in peripheral vessels within the indicated size range.

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

Conclusion

The non-clinical tests demonstrate that the subject device does not raise new questions of safety or effectiveness and, therefore, is substantially equivalent to the predicate device.