July 12, 2022

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

Re: K220415
Trade/Device Name: Protrieve Sheath
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: June 8, 2022
Received: June 9, 2022

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 (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)*
K220415

Device Name
Protrieve Sheath

Indications for Use *(Describe)*
The ClotTriever Thrombectomy System 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 Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).

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	July 11, 2022
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949-600-8433
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Name of Device	ClotTriever® Thrombectomy System
Device Trade Name	Protrieve™ Sheath
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	ClotTriever Thrombectomy System (K212632)
Reference device	Triever24 Catheter (K191710) Triever20 Catheter (K211013, K173672)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed to remove thrombi and emboli from the peripheral vasculature. The ClotTriever Thrombectomy System consists of ClotTriever 13 Fr and 16 Fr Sheaths and Protrieve Sheath ("Sheath"), and the ClotTriever/ClotTriever Bold Catheter ("Catheter"), each packaged separately. The sheath is an introducer sheath with a distal self-expanding funnel, aspiration port, and proximal hub. A dilator is provided to aid insertion and positioning of the sheath. Other provided accessories include a 60 cc large bore syringe that provides a vacuum source and collects aspirated contents. Radiopaque markers aid sheath positioning under fluoroscopic visualization. The dilator tip is radiopaque, and there is a radiopaque marker band near the distal end of the sheath. Target vessels include, but are not limited to, the iliofemoral, upper and lower extremity, inferior vena cava (IVC), and superior vena cava (SVC).

<table>
<tr><td>Indications for Use</td><td>The introduction of the Protrieve Sheath variant does not change the indications for use of the ClotTriever Thrombectomy System.
The ClotTriever Thrombectomy System 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 Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).</td></tr>
<tr><td>Device modifications</td><td>The purpose of this submission is to introduce a ClotTriever Sheath variant, the Protrieve Sheath, that is larger in diameter and comes in two additional lengths.

There have been no changes to the ClotTriever 13 Fr and 16 Fr Sheaths, the ClotTriever Catheter or the ClotTriever Bold Catheter.</td></tr>
<tr><td>Comparison of Technological Characteristics with the Predicate Device</td><td>The proposed device and predicate device have a similar design and materials of construction. With the exception of the modifications to the sheath ID/OD, dilator OD, sheath/dilator overall length, sheath/dilator durometer, funnel OD, and the funnel being preloaded in the sheath cover shaft, the predicate and proposed devices are the same. These modifications do not change the basic design or the principles of operation from the predicate device. There are no new questions of safety or efficacy. See table below for the comparison of the technological characteristics of the Protrieve Sheath with the predicate device.

There is no change of intended use or fundamental scientific technology between the proposed device and predicate device. The changes made for the Protrieve Sheath do not change the technological characteristics of the ClotTriever Thrombectomy System.
There have been no changes made to the ClotTriever Catheter or the ClotTriever Bold Catheter.

<table>
<tr><th>Device</th><th>Protrieve Sheath (Proposed)</th><th>ClotTriever Thrombectomy System Predicate (K212632)</th></tr>
<tr><td>Manufacturer</td><td>Inari Medical</td><td>Inari Medical</td></tr>
<tr><td>Product Code</td><td>QEW</td><td>QEW</td></tr>
<tr><td>Intended Use</td><td>Removal of thrombus and emboli from, and infusion of fluids into, the peripheral vasculature.</td><td>Removal of thrombus and emboli from, and infusion of fluids into, the peripheral vasculature.</td></tr>
<tr><td>Indications for Use</td><td>The ClotTriever Thrombectomy System 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.</td><td>The ClotTriever Thrombectomy System 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 Thrombectomy System is intended for use in the</td></tr>
</table>
</td></tr>
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Comparison of Technological Characteristics with the Predicate Device		The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).	peripheral vasculature including deep vein thrombosis (DVT).
	Device Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed to remove thrombi and emboli from the peripheral vasculature. The ClotTriever Thrombectomy System consists of ClotTriever 13 Fr, 16 Fr, and 20 Fr Sheaths ("Sheath") and the ClotTriever/ClotTriever Bold Catheter ("Catheter"), each packaged separately. The sheath is an introducer sheath with a distal self-expanding funnel, aspiration port, and proximal hub. A dilator is provided to aid insertion and positioning of the sheath. Other provided accessories include a 60 cc large bore syringe that provides a vacuum source and collects aspirated contents. Radiopaque markers aid sheath positioning under fluoroscopic visualization. The dilator tip is radiopaque, and there is a radiopaque marker band near the distal end of the sheath.	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed to remove thrombi and emboli from the peripheral vasculature. The ClotTriever Thrombectomy System consists of ClotTriever 13 Fr and 16 Fr Sheaths ("Sheath") and the ClotTriever/ClotTriever Bold Catheter ("Catheter"), each packaged separately. The sheath is an introducer sheath with a distal self-expanding funnel, aspiration port, and proximal hub. A dilator is provided to aid insertion and positioning of the sheath. Other provided accessories include a 60 cc large bore syringe that provides a vacuum source and collects aspirated contents. Radiopaque markers aid sheath positioning under fluoroscopic visualization. The dilator tip is radiopaque, and there is a radiopaque marker band near the distal end of the sheath.
	Principles of Operation	The ClotTriever/ClotTriever Bold 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/ClotTriever 20 Fr 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.	The ClotTriever/ClotTriever Bold 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.
	Sheath Shaft Materials	<u>Proximal segment:</u> Pebax 4533 (45D) SA 01 MED, 4% Violet C Hydrophilic Coating <u>Distal segment:</u> Pebax 3533 (35D) SA 01 MED, Propell, 4% Violet C	<u>Proximal segment:</u> Pebax 6333 (63D) SA 01 MED; Propell, 20% Barium Sulfate, 4% Violet C <u>Distal segment:</u> Pebax 7233 (72D) SA 01 MED; Propell, 20% Barium Sulfate, 4%Violet C

Comparison of Technological Characteristics with the Predicate Device	Sheath Shaft ID/OD	ID: 0.270” OD: 0.345”	ID: 0.215” OD: 0.248”
	Sheath Shaft Length	Model 60-100 Overall Length: 72 cm Effective Length: 54 cm Model 60-101 Overall Length: 50cm Effective Length: 32cm	Overall Length: 32 cm Effective Length: 15 cm
	Sheath Hub Materials	Model 60-100 Santoprene 251-70W232 + Lexan HP1-112, Polycarbonate Model 60-101 Santoprene 251-70W232 + Makrolon RX2530, Polycarbonate	Makrolon RX2530, Polycarbonate
	Mesh Funnel	0.0067” Nitinol wire	0.0055” Nitinol wire
	Mesh Funnel Length	Length: 1.24”	Length: 0.90”
	Mesh Funnel OD	OD: 33.5 mm	OD: 14 mm
	Dilator Materials	HDPE DMDA 8920+, 2% Titanium dioxide LDPE 640i, 20% Barium sulfate, 2% Titanium dioxide ABS, Cool Gray 6C	Pebax 72D, SA01 MED, Polyether block amide; 2% Titanium dioxide Pebax 55D SA01 MED, Polyether block amide; 20% Barium sulfate, 2% Titanium dioxide, Propell Pebax 72D SA01 MED, Polyether block amide; 20% Barium sulfate, 2% Titanium dioxide, Propell
	Dilator OD	OD: 0.264”	OD: 0.206”
	Dilator Length	Model 60-100 Length: 80 cm Model 60-101 Length: 58 cm	Length: 25 cm
	Hemostasis Valve	Tube Septum: Polyblend 1100-45A, Thermoplastic Polyurethane Elastomer Alloy, Loctite Adhesive Monofilament: Braided Polyethylene Terephthalate (Polyester)	Tube Septum: Silicone, Braided Nitinol #2, Silicone Adhesive Monofilament: Nylon
	Sideport Tubing with Stopcock and Quick Connect	Yes	Yes
	Guidewire compatibility	0.035”	0.035”

	Large Bore 60cc Syringe accessory	Large Bore 60cc Syringe Gen. 2: Spring-loaded release tab that self-locks to maintain the retracted position	Large Bore 60cc Syringe: Manual rotation of plunger to maintain the fully retracted position
	Shelf-Life	2 years	2 years
	Sterile	SAL 10^{-6}, EO	SAL 10^{-6}, EO
	How provided	Sterile, single use	Sterile, single use
Summary of substantial equivalence	The proposed device, the Protrieve Sheath, and the predicate device, the ClotTriever 16 Fr Sheath, have the same indications for use, intended use, principles of operation, and fundamental scientific technology. <u>Non-Clinical Testing</u> In accordance with the design failure modes and effects analysis, verification and validation tests were identified to support the substantial equivalence of the Protrieve Sheath to the predicate device. This testing demonstrated compliance with relevant product specifications. The following tests were performed on the proposed device to establish substantial equivalence: • Pouch Seal Visual Inspection and Dye Penetration • Usability • Visual and Dimensional Inspection • Radial Force • Guidewire Compatibility • Insertion/Retraction Force • Deployment/Retraction Force • Locking Cap Force and Unlocking Cap Torque • Kink Radius • Simulated Use, Track – Insertion Verification & Retraction Force of ClotTriever Catheter through Sheath • Dye Stain • Lubricity and Durability • Fluid Leakage • Air Leakage • Vacuum Testing • Push-Button Force Testing • Priming Volume • Flow Test • Dilator Retraction through Clot Analog • Clot Burden Removal • Burst Testing – Garrote Valve • Simulated Use, Track, Tensile & Torque – Sheath and Dilator • Simulated Use, Track, Rotation. & Torque – Garrote Valve • Simulated Use, Track, Rotation, & Torque Resistance - Sheath • Placement Resistance • Corrosion Resistance • Particulate Matter • Small Bore Connector Test • In Vivo Functional Testing/Radiopacity Verification		

Pouch peel and seal strength testing was leveraged from the Inari Medical Triever20 Catheter (K173672). The following testing was leveraged from K192036:

- Visual and Dimensional Inspection (*non-affected components*)
- Burst Testing – Flushing Stopcock
- Torque Testing – Flushing Stopcock
- Vacuum Testing – Flushing Stopcock
- Sterilization Validation

The following biocompatibility tests were performed on the proposed device as suggested by ISO 10993-1:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Toxicity
- Pyrogenicity
- Hemocompatibility – Hemolysis
- Hemocompatibility – Complement Activation
- Hemocompatibility – Thrombogenicity (*in vivo*)
- Hemocompatibility – Thrombogenicity (*in vitro)* (Platelet and Leukocyte)
- Hemocompatibility – Thrombogenicity (*in vitro*) (Partial Thromboplastin Time Test)

Clinical testing was not required to support substantial equivalence.

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

Conclusion

The proposed device modifications to the ClotTriever Thrombectomy System do not change its intended use nor do they change the principles of operation. The verification and validation results demonstrate that the proposed Protrieve Sheath is substantially equivalent to the predicate device.