March 7, 2023

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

Re: K230331
Trade/Device Name: Protrieve Sheath
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA, DYB
Dated: February 6, 2023
Received: February 7, 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 (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: 2023.03.07 13:28:40 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230331

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).

The Protrieve Sheath is indicated for use as a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.

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 6, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949-600-8433
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Device Name	Protrieve™ Sheath
Trade Name	Protrieve™ Sheath
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Primary product code	QEW
Secondary product codes	KRA, DYB
Regulatory class	II
Predicate device	Intri24™ Introducer Sheath (K212392)
Reference device	Protrieve™ Sheath (K220415)
Description	The Protrieve Sheath is a sterile, single-use over-the-wire introducer sheath with a hydrophilic coating, 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).
Indications for Use	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). The Protrieve Sheath is indicated for use as a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.

Device modifications

The purpose of this submission is a design modification to the Protrieve Sheath slide actuator specifically and to expand the indications for use statement to include using the Protrieve Sheath as a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.

There are no proposed changes to the intended use of the Protrieve Sheath.

There are no proposed changes to the intended use and design of the ClotTriever/ClotTriever BOLD Catheter and ClotTriever Sheaths (13 Fr and 16 Fr).

Comparison of Technological Characteristics with the Predicate Device

The predicate Intri24 Introducer Sheath is indicated to "Provide a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions." The proposed Protrieve Sheath's expanded indications for use are identical. Furthermore, the principles of operation and fundamental scientific technology of the proposed Protrieve Sheath and predicate device are substantially equivalent. Both devices act as a conduit for the insertion and removal of endovascular devices in the vasculature. The design and materials of construction of both devices are also substantially the same. The shafts of both devices contain a hydrophilic coating to reduce the insertion force through skin and tissue. Both sheaths also include an appropriately sized dilator (0.035" guidewire compatible) with a tapered tip to aid in dilation of the target vessel when inserting the sheath. Both sheaths contain a user-actuated hemostasis valve that allows for inserting or withdrawing endovascular devices through the sheath while minimizing blood loss.

Device	**Protrieve Sheath (Proposed)**	**Intri24 Introducer Sheath Predicate (K212392)**	**Protrieve Sheath Reference (K220415)**
Manufacturer	Inari Medical	Inari Medical	Inari Medical
Product Code	QEW, KRA, DYB	DYB	QEW, KRA
Indications for Use	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). The Protrieve Sheath is indicated for use as a conduit for the insertion of endovascular devices into the vasculature	The Intri24 Introducer Sheath is indicated to provide a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.	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).

	while minimizing blood loss associated with such insertions.		
Device Description	The Protrieve Sheath is a single-use, sterile medical device for use in the peripheral vasculature. The Protrieve Sheath is an introducer sheath with a hydrophilic coating, 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 Intri24 Introducer Sheath is a single-use, sterile medical device for use in the peripheral vasculature. The Intri24 Introducer Sheath is an introducer sheath consisting of a short single lumen catheter with a hydrophilic coating, proximal hemostasis valve, and stopcock with flush port. A radiopaque marker is positioned near the distal tip of the sheath to aid with fluoroscopic visualization. The Intri24 dilator is compatible with a 0.035" guidewire and has a tapered leading edge which aids insertion and positioning of the Intri24 Sheath.	The Protrieve Sheath is a single-use, sterile medical device for use in the peripheral vasculature. The Protrieve Sheath is an introducer sheath with a hydrophilic coating, 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 Protrieve Sheath and dilator are inserted over a pre-placed 0.035" guidewire into the vessel. Under fluoroscopic guidance, the funnel is deployed proximal to the target site. The Protrieve Sheath funnel is deployed by retracting the sheath's slide actuator back until it snaps into place. Once the funnel is deployed, the dilator is withdrawn through the sheath and from the patient entirely. The ClotTriever/ClotTriever BOLD Catheter or an	The Intri24 Introducer Sheath and dilator are inserted over a pre-placed 0.035" guidewire into the vessel towards the target treatment site using fluoroscopic imaging. After positioning, the dilator is detached from the hemostasis valve and withdrawn from the patient. An endovascular device is then advanced over the guidewire through the Intri24 Introducer Sheath to the targeted treatment site. Following the diagnostic or therapeutic procedure, the endovascular device is retracted through the Intri24 Introducer Sheath and removed from the patient.	The Protrieve Sheath and dilator are inserted over a pre-placed 0.035" guidewire into the vessel. Under fluoroscopic guidance, the funnel is deployed proximal to the target site. The Protrieve Sheath funnel is deployed by retracting the sheath's slide actuator back until it snaps into place. Once the funnel is deployed, the dilator is withdrawn through the sheath and from the patient entirely. The ClotTriever/ClotTriever BOLD Catheter is then advanced over the guidewire through the Protrieve Sheath to the targeted treatment site. The ClotTriever/ClotTriever

	endovascular device is then advanced over the guidewire through the Protrieve Sheath to the targeted treatment site. Following the diagnostic or therapeutic procedure, the ClotTriever/ ClotTriever BOLD Catheter or endovascular device is retracted through the Protrieve Sheath and removed from the patient. A 60 cc syringe is provided for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.		BOLD Catheter with the entrapped clot is retracted through the Protrieve Sheath and removed from the patient. A 60 cc syringe is provided for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.
Target Vessel	Peripheral vasculature. Target vessels include, but are not limited to, the iliofemoral, upper and lower extremity, inferior vena cava (IVC), and superior vena cava (SVC).	Peripheral vasculature.	Peripheral vasculature. Target vessels include, but are not limited to, the iliofemoral, upper and lower extremity, inferior vena cava (IVC), and superior vena cava (SVC).
Placement duration	< 24 hours	< 24 hours	< 24 hours
Sterilization	SAL 10^{-6}, EO	SAL 10^{-6}, EO	SAL 10^{-6}, EO
Shelf-life	2 years	2 years	2 years
How provided	Sterile, single use	Sterile, single use	Sterile, single use
Sheath shaft length	Undeployed length: 38 cm Deployed length: 32 cm	33 cm	Undeployed length: 32 cm Deployed length: 26 cm
Sheath shaft ID/OD	ID: 0.270” OD: 0.345”	ID: 0.314” OD: 0.344”	ID: 0.270” OD: 0.345”
Shaft coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating
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 4533 (45D) SA 01 MED, 20% BaSO4, 4% Violet C, Hydrophilic Coating <u>Distal segment:</u> Pebax 6333 (63D) SA 01 MED, 20% BaSO4, 4% Violet C	<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

Marker band	Platinum-iridium	Platinum-iridium	Platinum-iridium
Mesh Funnel	Length: 1.24” OD: 33.5 mm Material: 0.0067” Nitinol wire	N/A	Length: 1.24” OD: 33.5 mm Material: 0.0067” Nitinol wire
Dilator Materials	HDPE DMDA 8920+, 2% Titanium dioxide LDPE 640i, 20% Barium sulfate, 2% Titanium dioxide ABS, Cool Gray 6C	HDPE DMDA 8920+, 2% Titanium dioxide LDPE 640i, 20% Barium sulfate, 2% Titanium dioxide ABS, Cool Gray 6C	HDPE DMDA 8920+, 2% Titanium dioxide LDPE 640i, 20% Barium sulfate, 2% Titanium dioxide ABS, Cool Gray 6C
Dilator OD	0.264”	0.315”	0.264”
Dilator Length	25.15”	18.78”	22.96”
Sideport Tubing with Stopcock and Quick Connect	Yes	Yes	Yes
Guidewire compatibility	0.035”	0.035”	0.035”
Accessory	Large bore 60 cc syringe	N/A	Large bore 60 cc syringe

Summary of substantial equivalence

Non-Clinical Testing

In accordance with the design failure modes and effects analysis, verification tests were identified and performed only for the attributes impacted by the slide actuator modification to support substantial equivalence. Verification testing was not required for the expanded indications and the testing performed in K220415 remains applicable to support the use of the Protrieve Sheath as a conduit for the insertion of endovascular devices into the peripheral vasculature. The testing demonstrated compliance with relevant product specifications.

The following tests were performed for the slide actuator change on the proposed device to establish substantial equivalence:

- Simulated Use, Flushing – Protrieve Sheath
- Leakage Testing – Protrieve Sheath
- Tensile Testing – Protrieve Sheath

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

Clinical Testing

Clinical testing was not required to support substantial equivalence.

Conclusion

The proposed design modification of the Protrieve Sheath slide actuator does not change its intended use or principles of operation. The verification results demonstrate that the proposed Protrieve Sheath is substantially equivalent to the predicate device.

Expanding the indications for use statement to include using the Protrieve Sheath as a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions aligns with the current use of the device. The Protrieve Sheath is an introducer sheath for the insertion and removal of thrombectomy catheters in the peripheral vasculature. Similarly, the expanded indication allows the Protrieve Sheath to act as a conduit for the insertion and removal of endovascular devices into the peripheral vasculature. The proposed indication for the Protrieve Sheath does not raise new or different questions of safety or effectiveness.