October 29, 2025

Inari Medical
Rayee Patil
Sr. Regulatory Affairs Specialist
6001, Oak Canyon
Ste. 100
Irvine, California 92618

Re: K253323
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: September 23, 2025
Received: September 30, 2025

Dear Rayee Patil:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.10.29 15:19:40 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253323

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.

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.

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"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	October 28, 2025
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Rayee Patil Sr. Regulatory Affairs Specialist
Name of Device	Protrieve™ Sheath
Common name	Embolectomy Catheter
Regulation name	Embolectomy Catheter
Classification number	21 CFR 870.5150
Product code	QEW, KRA, DYB
Regulatory class	II
Predicate device	Inari Medical, Protrieve™ Sheath (K230331)
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 60cc 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.

<table>
<tr><td>Device Modifications</td><td>The purpose of this submission is for the incremental, non-significant modifications made to Protrieve Sheath since clearance was granted under K230331. Those non-significant modifications are:

1. To continue to meet global demand, Centerpiece was selected as an additional Sterilizer vendor for Protrieve Sheath. Qualifications were performed to establish the requirements needed to release Inari Medical Products from a single sterilization load, as established under Inari Medical's quality procedure. The test demonstrated that the product sterilized by Centerpiece met the requirements under ISO 11135 guidelines.

2. Minor dimensional and design changes were made to the garrote valve nipple, to improve its interaction with the rest of the valve assembly. Design verification testing was performed to evaluate the design change and the results documented show that the changes are acceptable

3. Centerpiece (Baja California, Mexico) was qualified as a new Sterilization supplier, and underwent qualification per ISO 11135:2014/Amd1:2018 Annex E. There's no change to the sterilization method, sterility assurance level, or how the device is provided. Testing to qualify this change was performed using the same methods as the cleared devices; and the results including EO residual test results, show that the product sterilized by Centerpiece meets the requirements to be called sterile under ISO 11135 guidelines.

4. The Instructions for Use (IFU) has been revised to replace "needless injection" with "needless injection flush port" in figure 1 of the IFU and in step #4 of the directions for use. The changes are being implemented to provide clarification to the IFU. This change of term "needleless injection" to "needleless injection flush port" clarifies the description of the part of the needless injection component which needs to be used for flushing. There are no changes to the device.

5. Two additional PTFE liner suppliers were qualified and added as secondary PTFE liner suppliers. All the suppliers' liners are identical with respect to dimensions and material. There is no change in manufacturing processes or material, and all the PTFE components being purchased from secondary suppliers are identical to the currently sourced components. The biocompatibility of PTFE liners was evaluated by Inari Medical. Design verification per using the same methods as the cleared devices was performed to evaluate the alternate liners in representative devices and the results show that the liners from the alternate supplier are acceptable for use.</td></tr>
<tr><td>Comparison of Technological Characteristics with the Predicate Device</td><td>
<table>
<tr><th>Device</th><th>Protrieve Sheath
Proposed Device (K253323)</th><th>Protrieve Sheath
Predicate device (K230331)</th></tr>
<tr><td>Manufacturer</td><td>Inari Medical, Inc.</td><td>Inari Medical, Inc.</td></tr>
<tr><td>Product code</td><td>QEW, KRA, DYB</td><td>QEW, KRA, DYB</td></tr>
<tr><td>Intended use</td><td>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.</td><td>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.</td></tr>
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	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 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.
	Principle 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 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.	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 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.
	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. 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
	Sheath shaft length	Undeployed length: 38 cm Deployed length: 32 cm	Undeployed length: 38 cm Deployed length: 32 cm
	Sheath shaft ID/OD	ID: 0.270" OD: 0.345"	ID: 0.270" OD: 0.345"
	Shaft coating	Hydrophilic coating	Hydrophilic coating

	Marker band	Platinum-iridium	Platinum-iridium
	Mesh Funnel	Length: 1.24” OD: 33.5 mm Material: 0.0067” Nitinol wire	Length: 1.24” OD: 33.5 mm Material: 0.0067” Nitinol wire
	Dilator OD	0.264”	0.264”
	Dilator Length	25.15”	25.15”
	Sideport Tubing with Stopcock and Quick Connect	Yes	Yes
	Sheath Shaft Liner Material	PTFE 1 Primary Supplier 2 Secondary Suppliers	PTFE 1 Primary Supplier
	Sterilization	SAL 10^{-6}, EO Sterilizer: Parter Sterilization Service (PSS), Centerpiece.	SAL 10^{-6}, EO Sterilizer: Parter Sterilization Service (PSS).
	Shelf-life	2 years	2 years
	How provided	Sterile, single use	Sterile, single use
	Guidewire compatibility	0.035”	0.035”
	Accessory	Large bore 60 cc syringe	Large bore 60 cc syringe

Summary of substantial equivalence

There is no change to the intended use, technological characteristics, principles of operation, or fundamental scientific technology between the proposed Protrieve Sheath and the predicate device. The Protrieve Sheath has the same indications for use as the predicate device, K230331.

Biocompatibility

The change proposed in this submission is the addition of 2 new suppliers for the PTFE material used in Protrieve Sheath. A representative Inari Medical device which uses the PTFE liner, from a worst-case surface area standpoint was tested for biocompatibility and the test results were leveraged for the Protrieve Sheath. These leveraged test results were previously also cleared for the Intri24 Introducer Sheath in K233646.

The passing results performed per ISO 10993-1 demonstrate that the subject device meets the biological safety requirements per ISO 10993-1.

Sterilization

The subject device 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.

Non-Clinical Testing

In accordance with the design failure modes and effects analysis, design verification testing was conducted on the worst-case representative device (Inari Medical’s Intri24 Introducer Sheath) to verify that the modified device continues to meet the design requirements of the product specifications.

The following tests were leveraged for the modified device, from Intri24 Introducer Sheath’s testing which was supported with a risk-based assessment and cleared in K233646.

- Locking Cap Force and Unlocking Cap Torque
- Low Pressure Fluid Leakage Testing, Sheath
- High Pressure Fluid Leakage Testing, Sheath with Blood Analog

	• Air Leakage Testing, Dilator Removal • Air Leakage Testing, Syringe Pullback • Vacuum Testing • Sheath Burst Neither animal testing nor clinical testing were required for the determination of substantial equivalence **Conclusion** The Protrieve Sheath has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports Protrieve Sheath's substantial equivalence to the predicate device.