December 18, 2023

Inari Medical, Inc.
Tosan Eweka
Principal Regulatory Affairs Specialist
6001 Oak Canyon, Suite 100
Irvine, California 92618

Re: K233815
Trade/Device Name: ClotTriever Sheath
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA, DYB
Dated: November 30, 2023
Received: November 30, 2023

Dear Tosan Eweka:

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.

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: 2023.12.18 11:55:40 -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

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)*
K233815

Device Name
ClotTriever 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 ClotTriever Sheaths are 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.

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510(K) SUMMARY

Date prepared	November 30, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Tosan Eweka Principal Regulatory Affairs Specialist
Trade Name	ClotTriever Sheath
Device Name	ClotTriever 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	Protrieve Sheath (K230331)
Description	The ClotTriever Thrombectomy System ("ClotTriever System") is a single-use over-the-wire catheter-based system used for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The system consists of ClotTriever Catheters, ClotTriever Sheaths and Protrieve Sheath, each packaged separately. The ClotTriever Sheath consist of a polymeric shaft with a distal self-expanding nitinol mesh funnel, a proximal hub with a hemostasis valve and a sideport tubing. The mesh funnel is deployed by retracting the slide actuator back until it snaps into place. The mesh funnel self-expands to the diameter of the vessel and serves as a backstop as clot is removed through the lumen of the sheath. A hemostasis valve is integrated into the proximal hub of the sheath to prevent blood loss from devices passing through it. The sideport tubing has a large-bore stopcock and a terminal quick-disconnect coupling for connection to the Large Bore 60 cc Syringe for the aspiration of clot. A pre-dilator is provided with the ClotTriever Sheaths, to expand the target vessel prior to sheath insertion. A dilator is provided to aid insertion and positioning of the sheath, while the loading tool facilitates insertion of the mesh funnel into the dilator.
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).

<table>
<tr><td></td><td>The ClotTriever Sheaths are 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>
<tr><td>Device Modifications</td><td>The purpose of this submission is to modify the indications for use statement to include use of the ClotTriever Sheaths as conduits for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.</td></tr>
<tr><td>Summary of substantial equivalence</td><td>The subject device and predicate device have the same intended use and indications for use. Both devices are intended to be used as conduits for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions. The subject device has the same principle of operation and similar technological characteristics as the predicate device. A tabular comparison between the predicate and subject device is provided below:
<table>
<tr><th></th><th>ClotTriever Sheaths (Subject Device)</th><th>Protrieve Sheath (Predicate Device)</th></tr>
<tr><td>Manufacturer</td><td>Inari Medical, Inc.</td><td>Inari Medical, Inc.</td></tr>
<tr><td>Model Designators</td><td>50-101 (13 Fr ClotTriever Sheath)
51-101 (16 Fr ClotTriever Sheath)</td><td>60-101 (20 Fr Protrieve Sheath)</td></tr>
<tr><td>Product Code</td><td>QEW, KRA, DYB</td><td>QEW, KRA, DYB</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.
The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).
The ClotTriever Sheaths are indicated for use as a conduit</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 peripheral vasculature including deep vein thrombosis (DVT).
The Protrieve Sheath is indicated for use as a conduit</td></tr>
</table>
</td></tr>
</table>

	for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.	for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.
Principles of Operation	The ClotTriever Sheath and dilator are inserted over a pre-placed 0.035" guidewire into the vessel. Under fluoroscopic guidance, the Sheath's mesh funnel is deployed proximal to the thrombus targeted for extraction. After deployment of the funnel, the dilator is withdrawn through the Sheath and from the patient entirely. The catheter or other endovascular device is then advanced over the guidewire through the ClotTriever Sheath to the targeted treatment site. Following the diagnostic or therapeutic procedure, the endovascular device is retracted through the ClotTriever Sheath and removed from the patient. The user-actuated hemostasis valve integrated into the Sheath hub allows for Insertion and withdrawal of endovascular devices.	The Protrieve Sheath and dilator are inserted over a pre-placed 0.035" guidewire into the vessel. Under fluoroscopic guidance, the Sheath's mesh funnel is deployed proximal to the thrombus targeted for extraction. After deployment of the funnel, the dilator is withdrawn through the Sheath and from the patient entirely. The catheter or other endovascular device is then advanced over the guidewire through the Protrieve Sheath to the targeted treatment site. Following the diagnostic or therapeutic procedure, the endovascular device is retracted through the Protrieve Sheath and removed from the patient. The user-actuated hemostasis valve integrated into the Sheath hub allows for Insertion and withdrawal of endovascular devices.
Target Vessel	Peripheral vessels	Peripheral vessels
Guidewire compatibility	0.035"	0.035"
Sheath shaft ID/OD	13 Fr ID – 0.180" 16 Fr ID - 0.215" 13 Fr OD - 0.210" 16 Fr OD - 0.248"	ID – 0.270" OD - 0.345"
Sheath length (deployed)	15 cm	32 cm

Dilator OD	13 Fr Sheath - 0.178” 16 Fr Sheath - 0.206”	0.264”
Dilator Length	10”	25”
Sterilization	SAL 10^{-6}, EtO	SAL 10^{-6}, EtO
Shelf-Life	2 years	2 years

Non-Clinical Testing

Verification testing provided in K180329 and K192036 remains applicable to support use of the ClotTriever Sheaths as conduits for the insertion of endovascular devices into the peripheral vasculature.

Clinical Testing

Clinical testing was not required to support substantial equivalence.

Conclusion

The change to the Indications for Use does not raise new or different questions of safety and effectiveness. Results from previously conducted verification testing demonstrate that the subject device is substantially equivalent to the predicate device. The subject device is therefore substantially equivalent to the predicate device.