September 27, 2024

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

Re: K242557
Trade/Device Name: ClotTriever XL Catheter (41-102)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: August 27, 2024
Received: August 28, 2024

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 (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: 2024.09.27 08:49:33 -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.

Submission Number *(if known)*

K242557

Device Name

ClotTriever XL Catheter (41-102)

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.

510(K) SUMMARY

Date prepared	September 26, 2024
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 XL Catheter (41-102)
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	Inari Medical, ClotTriever XL Catheter (K223210)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device system designed to remove thrombi and emboli from the peripheral vasculature. The ClotTriever XL Catheter is intended for vessels 10 to 28 mm in the peripheral vasculature. The ClotTriever Thrombectomy System consists of the 16Fr ClotTriever Sheath ("ClotTriever Sheath"), Protrieve Sheath and the ClotTriever XL Catheter (“Catheter”), each packaged separately. The ClotTriever XL Catheter is a coaxial catheter assembly with a distal coring element and collection bag for retrieving thrombus. The proximal handle controls the expansion of the collection bag via the inner catheter. The outer shaft constrains the coring element and collection bag prior to deployment. Stopcocks and Luer connectors are provided for de-airing the ClotTriever XL Catheter shafts. To aid in fluoroscopic visualization, the distal tip is radiopaque and radiopaque marker bands are located on the intermediate catheter to identify the proximal end of the coring element, and on the outer catheter to identify the distal end of ClotTriever XL outer catheter.
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).

Device Modifications	The purpose of this submission is a device labeling correction of the Instructions for Use (IFU) for the ClotTriever XL Catheter. The modifications included updates to the contraindications, warnings, and procedural techniques, specifically relating to the venous access site, retracting the catheter cranial to caudal, removal of excessive clot volume and the potential risk of thrombus embolization.
Comparison of Technological Characteristics with the Predicate Device	There is no change to the intended use, indications for use, technological characteristics, principles of operation, or fundamental scientific technology between the proposed ClotTriever XL Catheter and the predicate device.
Summary of substantial equivalence	The proposed ClotTriever XL Catheter and the predicate device have the same intended use, indications for use, technological characteristics, principles of operation, and fundamental scientific technology. **Non-Clinical Testing** In accordance with the design failure modes and effects analysis, design validation testing was only performed on the attributes impacted by the IFU modifications. The following tests were performed: • Simulated Use – Clot Burden • Simulated Use – Tensile Testing **Clinical Testing** Clinical testing was not required for the determination of substantial equivalence. **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. **Conclusion** The labeling modification does not change the intended use, indications for use, technological characteristics, principles of operation, or fundamental scientific technology between the proposed ClotTriever XL Catheter and the predicate device. Therefore, the ClotTriever XL Catheter is deemed to be substantially equivalent to the predicate device.