October 18, 2021

Inari Medical, Inc.
Larry Boucher
Regulatory Affairs Manager
9 Parker, Suite 100
Irvine, California 92618

Re: K212632
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: October 7, 2021
Received: October 8, 2021

Dear Larry Boucher:

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)*
K212632

Device Name
ClotTriever Thrombectomy System

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	August 17, 2021
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949-600-8433
Contact person	Larry Boucher Regulatory Affairs Manager
Name of Device	ClotTriever Thrombectomy System
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II
Predicate device	ClotTriever Thrombectomy System (K210689)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed for use in the peripheral vasculature. The ClotTriever Thrombectomy System consists of the ClotTriever Sheaths, the ClotTriever Catheter, and the ClotTriever Bold Catheter. The ClotTriever Sheaths are comprised of a reinforced polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port, and a proximal hemostatic valve. The ClotTriever Catheter and the ClotTriever Bold Catheter are comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Three ports terminating in stopcocks are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the Sheath, ClotTriever Catheter and ClotTriever Bold Catheter distal tips are radiopaque. Other accessories provided with the ClotTriever Sheath include a pre-dilator, a funnel loading tool and a Large Bore 60 cc syringe.
Indications for Use	The changes proposed for the ClotTriever Bold Catheter do 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).

Device modifications	The purpose of this submission is to introduce the ClotTriever Bold Catheter that includes the following modifications from the currently cleared ClotTriever Catheter. • Increased wall thickness specification of the coring element from 0.258 mm to 0.305 mm • ClotTriever Bold outer catheter extended the length of the Violet C colorant to replace the distal segment of Cool Grey colorant • ClotTriever Bold outer catheter distal tip changed durometer from 63D Pebax to 55D Pebax • Proximal attachment of the coring element to the intermediate catheter shaft is updated There have been no changes to the ClotTriever Sheath.
Comparison of Technological Characteristics with the Predicate Device	The proposed device and predicate device have a similar design and materials of construction. With the exception of the modifications to the coring element, the outer shaft's distal segment colorant and tip durometer, and proximal attachment of the coring element to intermediate shaft, the predicate and proposed devices are the same device. These modifications do not change the basic design or the principles of operation from the predicate device. There are no new or different questions of safety or efficacy. There is no change of intended use or fundamental scientific technology between the proposed device and predicate device. The changes made for the ClotTriever Bold Catheter do not change the technological characteristics of the ClotTriever Thrombectomy System. There have been no changes made to the ClotTriever Sheath.
Summary of substantial equivalence	The proposed device, the ClotTriever Bold Catheter, and the predicate device, the ClotTriever Catheter, 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 ClotTriever Bold Catheter 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: • Visual and Dimensional Inspection • ClotTriever Sheath Compatibility • Deployment/Retraction Force • Kink Radius • Fluid Leakage, Sheath • Vacuum Leakage, Sheath • Simulated Use, Track & Rotation

	• Simulated Use, Track & Tensile The following testing was leveraged from the predicate device (K210689): • Pouch Seal Visual Inspection and Dye Penetration • Pouch, Peel, Seal Strength • Visual and Dimensional Inspection (*non-affected components*) • Guidewire Compatibility • Conical Fittings with 6% Luer Taper • Retraction Force of Handle • Fluid Leakage, Catheter • Air Leakage, Sheath • Corrosion Resistance • Simulated Use, Track & Tensile (*non-affected components*) • Handle Torque • Particulate Matter • In Vivo Functional Testing/Radiopacity Verification • Biocompatibility Validation • Sterilization Validation Clinical testing was not required for the determination of substantial equivalence. Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications. <u>Conclusion</u> The proposed device modifications to the ClotTriever Thrombectomy System does not change its intended use nor does it change the principles of operation. With consideration of the results of the testing, it can be concluded that the proposed ClotTriever Bold Catheter is substantially equivalent to the predicate device.