October 10, 2018

Inari Medical
Eben Gordon
Vice President, RA/QA
9272 Jeronimo Road
Suite 124
Irvine, California 92618

Re: K182531
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: September 13, 2018
Received: September 14, 2018

Dear Mr. Gordon:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
For 2018.10.10 19:33:20 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182531

Device Name
ClotTriever Thrombectomy System

Indications for Use *(Describe)*

The ClotTriever Thrombectomy System consists of the ClotTriever Catheter and ClotTriever Sheath. The ClotTriever Thrombectomy System is indicated for:

- The non-surgical removal of soft 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.

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	September 13, 2018
Name	Inari Medical, Inc. 9272 Jeronimo Road, Suite 124 Irvine, CA 92618 949.600.8433 x114
Contact person	Eben Gordon Vice President, Regulatory Affairs & Quality Assurance
Trade name	ClotTriever Thrombectomy System
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	DXE
Regulatory class	II
Predicate device	Inari Medical's ClotTriever Thrombectomy System (K180329)
Reference devices	Inari Medical's ClotTriever Thrombectomy System (K173470) Inari Medical's ClotTriever Thrombectomy System (K163549)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed for use in the peripheral vasculature. The ClotTriever Thrombectomy System is comprised of the ClotTriever Sheath and the ClotTriever Catheter. The ClotTriever Sheath consists of a polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port, and a proximal hemostatic valve. A dilator is provided to aid insertion. Other provided accessories include the funnel loading tool and a 60 cc syringe. The ClotTriever Catheter consists of polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. At the proximal end of the catheter is a handle used to enable tensioning of the coring element. Two ports terminating in stopcocks are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the dilator and ClotTriever Catheter distal tips are radiopaque.
Indications for Use	The ClotTriever Thrombectomy System consists of the ClotTriever Catheter and ClotTriever Sheath. The ClotTriever Thrombectomy System is indicated for: • The non-surgical removal of soft 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.
Device modifications	The changes to the ClotTriever Thrombectomy System are:

- Decrease in the length of the ClotTriever Catheter's thrombus collection bag from 34 cm to 19 cm
- Decrease in the deployed length from 125 cm to 105 cm
- Replacement of the off-the-shelf 60 cc VacLok Syringe and Clot Reservoir with a large bore 60 cc VacLok Syringe.

Summary of substantial equivalence

There is no change of intended use or fundamental scientific technology between the modified and predicate devices.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the modified ClotTriever Thrombectomy System to the predicate device. This testing demonstrated compliance with relevant product specifications. These tests included:

- Visual & Dimensional Inspections
- Retraction Force of Handle
- Syringe Leak Testing
- Syringe Vacuum Testing
- Syringe Tensile Testing
- Clot burden Removal Performance Test
- Simulated Use, Tensile Test

Clinical testing was not required for the determination of substantial equivalence.

Conclusion

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications and intended use. Based upon the same intended use and principle of operation, technology, and non-clinical testing it is concluded that the modified ClotTriever Thrombectomy System is substantially equivalent to the predicate device.