April 9, 2018

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

Re: K180329
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: March 12, 2018
Received: March 13, 2018

Dear Eben 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for Kenneth J. Cavanaugh -S

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)*

K180329

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	February 5, 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 (K173470)
Reference devices	Inari Medical's FlowTriever Retrieval/Aspiration System (K173672) Inari Medical's Infusion Aspiration Catheter System (K143563) Merit Medical Systems' VacLok Vacuum Syringe (K163597)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device system designed for use in the peripheral vasculature. The ClotTriever Thrombectomy System consists 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 a clot reservoir, a funnel loading tool, and a 60 cc syringe. The ClotTriever Catheter consists of four pre- assembled polymeric coaxial catheters 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:

- Reduction in the length of the ClotTriever Sheath from 26 cm to 15 cm.
- Reduction in the length of the Dilator to match the Sheath change.
- An outer shaft has been added to the Dilator to aid in its removal from the ClotTriever Sheath after the funnel has been deployed.
- Decrease in the Dilator tip taper and hardness.
- Pre-loading of the Dilator into ClotTriever Sheath prior to final packaging.
- Replacement of the hemostasis valve with a user actuated hemostasis valve in the ClotTriever Sheath's proximal hub.
- Addition of a stopcock in the sideport tubing.
- Elimination of the Valve Dilator, Aspiration Insert, Flush Port Adapter, and tubing clamp components.
- Replacement of the 60 cc Monoject Syringe with the 60 cc VacLok Vacuum 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:

- Pouch Seal Inspection
- Dye Penetration Inspection
- Pouch Peel Test
- Visual & Dimensional Inspections: ClotTriever Sheath, Dilator, Clot Reservoir & Loading Tool
- Guidewire Compatibility Verification
- Insertion Force – ClotTriever Dilator Handle into Sheath Hub
- Retraction Force – Dilator Handle from Sheath Hub
- Deployment Force – ClotTriever Sheath from Dilator
- Engagement Force – Dilator Handle
- Retraction Force – Dilator Thru ClotTriever Sheath
- Retraction Force – Dilator Handle
- Insertion Verification – ClotTriever Delivery Catheter thru Sheath
- Retraction of the ClotTriever Catheter Thru ClotTriever Sheath
- Kink Resistance/ Radius Verification – ClotTriever Sheath & Dilator
- Leakage Verification, ClotTriever Sheath
- Leakage Verification, ClotTriever Dilator
- Leakage Verification, Clot Reservoir
- Air Leakage, ClotTriever Sheath
- Clot Reservoir Check Valve Cracking Pressure

- Vacuum Testing, ClotTriever Sheath
- Vacuum Testing, ClotTriever Clot Reservoir
- Push-Button Force Testing – Garrote Valve
- Fluid Test Thru ClotTriever Sheath/Dilator
- Corrosion Resistance
- ClotTriever Dilator Retraction in Clot Analog
- Simulated Use, Track and Tensile – ClotTriever Dilator
- Simulated Use, Track and Tensile – ClotTriever Sheath
- Simulated Use, Tensile – ClotTriever Clot Reservoir
- Simulated Use Track and Turn-to-Failure, ClotTriever Sheath
- Torque Testing – Dilator
- Torque Testing – Garrote Valve
- Torque Testing – Flushing Stopcock
- Burst Testing – Garrote Valve
- Burst Testing – Flushing Stopcock
- Particulate Evaluation

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.