DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 16, 2017

Inari Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K163549
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: February 8, 2017
Received: February 10, 2017

Dear Mr. Job:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163549

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	November 8, 2016
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	Infusion Aspiration Catheter System (K143563)
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 with tubing clamp, and a proximal hemostatic valve. An obturator is provided to aid insertion. Other provided accessories include a clot reservoir, a flush port adapter, an aspiration insert and a 60 ml syringe. The ClotTriever Catheter consists of three (3) pre-assembled polymeric coaxial catheters terminating in an expandable member and tissue collection net. At the proximal end of the catheter is a handle used to enable expansion of the expandable member and net. Two ports terminating in stopcocks are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the ClotTriever Sheath obturator and ClotTriever Catheter distal tips are radiopaque, and radiopaque marker bands are located on the intermediate shaft at the proximal end of the expandable member, and at the distal ends of the ClotTriever Sheath shaft and ClotTriever Catheter outer shaft.
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.

Summary of substantial equivalence

The ClotTriever Thrombectomy System and the predicate device have the same intended use: removal of obstructing material (including emboli and thrombi) from blood vessels.

The principle of operation is the same for ClotTriever Thrombectomy System and the Infusion Aspiration Catheter System – expanding nitinol structures are drawn through the vessel obstruction to capture clot and restore blood flow.

The ClotTriever Thrombectomy System and Infusion Aspiration Catheter System have similar materials of construction. Both use nitinol metal structures to remove the obstruction and have thermoplastic polymer catheter shafts. The ClotTriever Thrombectomy System and Infusion Aspiration Catheter System share the same hazard of a broken or protruding nitinol wire causing vessel puncture. To mitigate this possibility, the nitinol structures are 100% inspected twice for broken and protruding nitinol braids during the manufacturing process.

The expanded diameter for the ClotTriever Catheter is 16 mm which is within the range for the Infusion Aspiration Catheters of 12.5 mm to 22.3 mm for (models 10-101 and 10-103).

The ClotTriever Catheter is compatible with the 13 Fr ClotTriever Sheath versus the Aspiration Guide Catheter which is compatible with a 20 Fr sheath. The ClotTriever's smaller profile is inherently safer than the larger predicate device.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing was identified to support the substantial equivalence of the ClotTriever Thrombectomy System.

This testing demonstrated compliance with relevant standards (e.g. ISO 10555-1, ISO 594-1/2, etc.) and product specifications. These tests included:

- Pouch seal and dye penetration
- Pouch peel, seal strength
- Visual and dimensional inspections
- Guidewire compatibility
- Deployment Force of ClotTriever Sheath from Dilator
- Retraction Force of Dilator through ClotTriever Sheath
- Insertion of Delivery Catheter through ClotTriever Sheath
- Deployment Force of ClotTriever from Delivery Catheter
- Retraction Force of Handle to Expand/Collapse ClotTriever
- Retraction Force of ClotTriever into Delivery Catheter
- Retraction Force of ClotTriever Catheter through ClotTriever Sheath
- ClotTriever Sheath/Dilator Kink Radius
- ClotTriever Device Kink Radius

- Leakage Testing, ClotTriever Sheath and Accessories
- Leakage Testing, ClotTriever Sheath and Flush Port
- Leakage Testing, ClotTriever Device Hemostasis Valves
- Air Leakage, ClotTriever Sheath
- Leakage Testing, ID of ClotTriever Device w/Guidewire in Place
- Vacuum Testing ClotTriever Sheath
- Test Conical Fittings with 6% Luer Taper, Dilator
- Flow Test Through ClotTriever Sheath/Dilator
- Corrosion Resistance
- Simulated Use Track & Tensile, ClotTriever Sheath, Dilator, Clot Reservoir
- Simulated Use Track & Tensile ClotTriever Catheter
- Simulated Use Track & Turn-to-Failure, ClotTriever Sheath and Accessories
- Simulated Use Track & Turn-to-Failure, ClotTriever Catheter
- Torque Testing, ClotTriever Handle
- Torque Testing, Clot Reservoir Luer Activated Valve
- Particulate Matter

Biocompatibility testing in accordance with ISO 10993-l:

- Cytotoxicity
- Guinea pig maximization sensitization
- Intracutaneous irritation
- Acute systemic toxicity
- Material mediated pyrogen
- Bacterial mutagenicity
- Hemolysis, direct contact and extract method
- Complement activation
- Thromboresistance
- USP Physicochemical

The shelf life of the ClotTriever Thrombectomy System is 12 months from the date of manufacture based on accelerated aging studies. Verification testing was conducted on sterilized (ethylene oxide), accelerated-aged devices to support the 12 months shelf life.

Package integrity testing was conducted according to ISO 11607-1/2 guidelines. These tests included:

- Pouch seal and dye penetration
- Pouch peel, seal strength

Acute evaluation of the safety and performance of the ClotTriever Thrombectomy System was successfully performed in a bovine model.

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

Conclusion

Test results demonstrated that all acceptance criteria were met, and, therefore, the device conforms to established product specifications and intended use.

Based upon the technology, materials, intended use, non-clinical testing, and

animal study results, it is concluded that the ClotTriever Thrombectomy System is substantially equivalent to the Infusion Aspiration Catheter System. These results demonstrate that the ClotTriever Thrombectomy System is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified above.