



December 4, 2017

Inari Medical, Inc.
Mr. Eben Gordon
Vice President, Regulatory Affairs and Quality Assurance
9272 Jeronimo Road, Suite 124
Irvine, California 92618

Re: K173470
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 7, 2017
Received: November 8, 2017

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. 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

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173470

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 7, 2017
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	ClotTrievers Thrombectomy System
Common name	Embolectomy catheter
Regulation Name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	DXE
Regulatory class	II
Predicate devices	Inari ClotTrievers Thrombectomy System (K163549)
Description	<p>The ClotTrievers Thrombectomy System is a single-use, sterile medical device system designed for use in the peripheral vasculature. The ClotTrievers Thrombectomy System consists of the ClotTrievers Sheath and the ClotTrievers Catheter. The ClotTrievers 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. A dilator is provided to aid insertion. Other provided accessories include a clot reservoir, a flush port adapter, an aspiration insert, funnel loading tool, and a 60 cc syringe. The ClotTrievers 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 ClotTrievers Catheter distal tips are radiopaque, and radiopaque marker bands are located on the coring element shaft at the proximal end of the expandable coring element, and at the distal ends of the ClotTrievers Sheath and ClotTrievers Catheter outer shaft.</p>
Indications for Use	<p>The ClotTrievers Thrombectomy System consists of the ClotTrievers Catheter and ClotTrievers Sheath. The ClotTrievers Thrombectomy System is indicated for:</p> <ul style="list-style-type: none">• 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. <p>The ClotTrievers Thrombectomy System is intended for use in the peripheral vasculature.</p>

Device modifications	The changes to the ClotTrierer Thrombectomy System are: <ul style="list-style-type: none">• Implement a collapsible clot collection bag• Shortening the handle from approximately 23.5 cm to approximately 12.7 cm• Switch to a 0.018” guidewire compatibility for the ClotTrierer Catheter
Summary of substantial equivalence	There is no change of intended use or fundamental scientific technology between the proposed 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 ClotTrierer Thrombectomy System to the predicate device. This testing demonstrated compliance with relevant product specifications. These tests included:

- Pouch Seal Inspection
- Packaging Inspection
- Visual & Dimensional Inspections
- Guidewire Compatibility Verification
- Deployment Force – Net/Coring Element from Delivery Catheter
- Retraction Force – Net/Coring Element into Delivery Catheter
- Retraction Force – ClotTrierer Catheter Thru ClotTrierer Sheath
- Kink Resistance/ Radius Verification – ClotTrierer Catheter
- Leakage Verification, ClotTrierer Catheter
- Leakage Verification, ClotTrierer Catheter ID with Guidewire in Place
- Simulated Use Track and Tensile – ClotTrierer Catheter
- Clot Burden Removal Test
- Performance Test - Thrombus Removal Characterization

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 ClotTrierer Thrombectomy System is substantially equivalent to the predicate device.