May 17, 2018

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

Re: K180466
Trade/Device Name: FlowTriever Retrieval/Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: March 7, 2018
Received: March 8, 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,

Nicole G. Ibrahim -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180466

Device Name
FlowTriever Retrieval/Aspiration System

Indications for Use *(Describe)*
The FlowTriever Retrieval/Aspiration System consists of the FlowTriever Catheter, Aspiration Guide Catheter, and Retraction Aspirator. The FlowTriever Retrieval/Aspiration System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

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 K180466

Date prepared	February 16, 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	FlowTriever Retrieval/Aspiration 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)
Reference device	EkoSonic Endovascular System (K140151)
Description	The FlowTriever Retrieval/Aspiration System is a single-use over-the-wire catheter-based system for the minimally invasive treatment of pulmonary embolism. The system is comprised of three main components packaged separately: • Aspiration Guide Catheter • FlowTriever Catheter (available in 3 sizes: 6-10 mm, 11-14 mm, and 15-18 mm) • Retraction Aspirator The FlowTriever Catheter is inserted through the Aspiration Guide Catheter and advanced to the thrombus. Self-expanding wireform disks are deployed to engage thrombus by retracting the outer delivery catheter. The hand-lever operated Retraction Aspirator simultaneously aspirates fluids and retracts the FlowTriever Catheter with thrombus into the Aspiration Guide Catheter to capture clot and restore blood flow.

Indications for Use

The FlowTriever Retrieval/Aspiration System consists of the FlowTriever Catheter, Aspiration Guide Catheter, and Retraction Aspirator. The FlowTriever Retrieval/Aspiration System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

Summary of substantial equivalence

The purpose of this submission is to expand the indications for use of the FlowTriever/Aspiration System for the treatment of pulmonary embolism and propose device design changes.

The FlowTriever Retrieval/Aspiration System and the predicate device have the same intended use: removal of obstructing material (including emboli and thrombi) from blood vessels by mechanical means.

The device design changes do not significantly change the underlying technological characteristics and do not raise different questions of safety and effectiveness compared to the predicate.

Non-Clinical Testing

In alignment with the Design Failure Modes and Effects Analysis, verification and validation testing was identified in support of the FlowTriever Retrieval/Aspiration System. These tests included:

- Pouch seal visual inspection and dye penetration
- Pouch peel, seal strength
- Visual and dimensional inspections
- Guidewire compatibility
- Snap fit, Dilator Luer to Guide Catheter hemostasis valve
- Deployment force of Wireform Catheter from Delivery Catheter
- Retraction force of Wireform Catheter into Delivery Catheter
- Retraction force of Wireform Catheter into Guide Catheter
- Leakage testing of Wireform Catheter with guidewire in place
- Guide Catheter/Infusion Wireform Catheter kink radius
- Liquid leakage under pressure
- Leakage testing, devices with Guide Catheter hemostasis valve
- Test of conical fittings with 6% Luer taper
- Air leakage into hub assembly during aspiration
- Retraction Aspirator retraction testing
- Tube Set Check Valve and vent plug inspection
- Tube set, leakage
- Tube Set check valve cracking pressure
- Determination of flow rate through catheter
- Corrosion resistance
- Tube set tensile strength

- Particulate matter evaluation
- Burst pressure and burst testing
- Simulated Use Tracking and tensile, Delivery Catheter, Guide Catheter, Dilator, Wireform Catheter
- Simulated Use tracking and torque

Biocompatibility testing in accordance with ISO 10993-l:

- MEM elution
- ISO Guinea Pig Maximization Sensitization
- ISO Intracutaneous Irritation
- Acute systemic toxicity
- Hemolysis, direct contact and extract method
- Complement Activation, C3a and SC5b-9 Assay
- Unactivated Partial Thromboplastin Time (UPTT) Test

Acute evaluation of the safety and performance of the FlowTriever Retrieval/Aspiration System was successfully performed in swine pulmonary arteries. Specifically the ability to place and deploy the device, the fluoroscopic visibility and the ability to infuse fluid through the catheters was evaluated, and all acceptance criteria were successfully met. In addition, the histological evaluation of the vessel specimens after use of the test devices was performed and demonstrated no significant gross or histopathological findings in treated vessels.

Clinical Testing

Inari Medical conducted the FlowTriever Pulmonary Embolectomy Clinical ("FLARE") Study, a prospective, single-arm, multicenter study, to evaluate the safety and effectiveness of the FlowTriever System for the treatment of acute pulmonary embolism (PE). A total of 106 subjects were enrolled at 18 investigational sites. The primary safety endpoint was the composite of major adverse events (MAE), defined as device-related death, major bleeding and treatment-related adverse events (clinical deterioration, pulmonary vascular injury, or cardiac injury) measured at 48 hours. The primary effectiveness endpoint was reduction in RV/LV ratio from baseline to 48 hours. The study met the performance goals for the primary study endpoints. Refer to the Instruction for Use for detailed clinical study information.

Conclusion

Compared to the predicate device, the expanded indication and device modifications to the FlowTriever Retrieval/Aspiration System do not change the intended use and the technological differences do not raise different questions of safety and effectiveness. Based on the results of pre-clinical testing and the FLARE Clinical Study, the data supports that the FlowTriever Retrieval/Aspiration System is substantially equivalent to the predicate device.