June 17, 2018

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

Re: K181325
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: May 17, 2018
Received: May 18, 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 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,

Brian D. Pullin -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)*
K181325

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

Date prepared	June 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	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 devices	Inari FlowTriever Retrieval/Aspiration System (K180466) (Primary Predicate) Inari FlowTriever Retrieval/Aspiration System (K173672)
Description	The FlowTriever Retrieval/Aspiration System is a single-use over-the-wire catheter-based system for the minimally invasive treatment of thromboemboli in the peripheral vasculature. 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.

Device modifications

The Aspiration Guide Catheter and Retraction Aspirator Tubing Set were modified from the versions cleared under K180466 to allow the removal of the FlowTriever Catheter from the patient without the simultaneous removal of the Aspiration Guide Catheter. In doing so, if another embolectomy pass is attempted, the step of re-introducing the Aspiration Guide Catheter and crossing the right heart is eliminated. All other components of the FlowTriever Retrieval/Aspiration System are identical to those cleared under K180466.

The modifications to the Aspiration Guide Catheter and Retraction Aspirator included the following:

- Replacing the hemostasis valve with a user-actuated hemostasis valve in the Aspiration Guide Catheter's proximal hub.
- Replacing the off-the-shelf stopcock with a large bore stopcock in the side port tubing.
- Increasing the lumen diameters of the tubing and connector in the fluid path between the Aspiration Guide Catheter to the collection bag.
- Replacing the checkvalve component in the Tubing Set with a clot reservoir to prevent clot from plugging distal checkvalve as it is transported to the collection bag.

These modifications made the Aspiration Guide Catheter and Retraction Aspirator Tubing Set identical to the Aspiration Guide Catheter and Retraction Aspirator Tubing Set cleared under K173672. As all of the other components of the FlowTriever Retrieval/Aspiration System were already identical to those cleared under K173672, the modifications make the proposed FlowTriever Retrieval/Aspiration System identical to the one cleared under K173672.

Summary of substantial equivalence

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

The FlowTriever Retrieval/Aspiration System has the same indication for use as the primary predicate, K180466. The indication for use for the additional predicate, K173672, only differs in that it does not include treatment of pulmonary embolism.

The FlowTriever Retrieval/Aspiration System has been modified from the version cleared under K180466 to be identical the version cleared under K173672.

<u>Non-Clinical Testing</u>

The FlowTriever Retrieval/Aspiration System is identical to the version cleared under K173672. Appropriate rationales were provided to support that the testing

provided under K173672 may be appropriately leveraged to support clearance of this device for the proposed intended use. Therefore, additional verification testing is not necessary to establish compliance to design specifications.

Conclusion

The proposed device modifications to the FlowTriever Retrieval/Aspiration System do not change its intended use or raise different questions of safety and effectiveness. With consideration of the results of the testing leveraged from K173672, it can be concluded that the proposed FlowTriever Retrieval/Aspiration System is substantially equivalent to the predicate device.