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

August 25, 2015

Inari Medical, Inc.
c/o Mr. Eben Gordon
Vice President, Regulatory Affairs & Quality Assurance
9272 Jeronimo Road, Suite 124
Irvine, CA 92618

Re: K152097
Trade/Device Name: Retraction Aspirator
Regulation Number: 21 CFR 870.5150
Regulation Name: Embelectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: July 26, 2015
Received: July 28, 2015

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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kenneth J. Cavanaugh -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152097

Device Name

Retraction Aspirator

Indications for Use *(Describe)*

The Retraction Aspirator is intended to be used with the FlowTriever Retrieval/Aspiration System to facilitate the simultaneous aspiration and withdrawal of the FlowTriever Catheter into the Guide Catheter.

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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6 510(K) SUMMARY

Date prepared	August 24, 2015
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	Retraction Aspirator
Common name	Embolectomy catheter
Regulation Name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	DXE
Regulatory class	II
Predicate devices	Inari Medical Infusion Aspiration Catheter System (K143563)
Description	The Retraction Aspirator facilitates the simultaneous aspiration and withdrawal of the FlowTriever Catheter into the Guide Catheter. The hand-lever operated Retraction Aspirator, with its integrated clutch, is fitted with a vacuum syringe and collection container. Operating the Retraction Aspirator lever simultaneously retracts the FlowTriever Catheter into the Guide Catheter and aspirates fluid.
Indications for Use	The Retraction Aspirator is intended to be used with the FlowTriever Retrieval/Aspiration System to facilitate the simultaneous aspiration and withdrawal of the FlowTriever Catheter into the Guide Catheter.
Summary of substantial equivalence	No changes have been made to the Retraction Aspirator since the original clearance on February 3, 2015 (K143563). The device design, technology, materials, processes, etc. have not been changed with this application. **Non-Clinical Testing** Non-clinical test results for the Retraction Aspirator were submitted in premarket notification K143563. No changes have been made to the device therefore additional testing was not necessary. Clinical testing was not required for the determination of substantial equivalence. **Conclusion** The Retraction Aspirator is a component of the FlowTriever System and has not

been modified from the device cleared under premarket notification (510(k)) number K143563. The Retraction Aspirator will be commercially distributed individually with the same intended use apart from the FlowTriever System. The information provided in this submission demonstrates that the Retraction Aspirator that is the subject of this 510(k) is substantially equivalent to the legally marketed predicate device.