June 17, 2019

Inari Medical
Eben Gordon
Vice President, RA/QA
9272 Jeronimo Rd., Suite 124
Irvine, CA 92618

Re: K191368
Trade/Device Name: FlowTriever Retrieval/Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: May 21, 2019
Received: May 22, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K191368

Device Name
FlowTriever Retrieval/Aspiration System

Indications for Use *(Describe)*
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 - Special 510(k)

Date prepared	May 21, 2019
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	QEW
Regulatory class	II
Predicate device	Inari FlowTriever Retrieval/Aspiration System (K183198)
Reference device	Inari FlowTriever Retrieval/Aspiration System (K182233)
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 and for the treatment of pulmonary embolism. The system is comprised of two main components packaged separately: • Triever Catheters (available in 2 sizes: 16 Fr and 20 Fr) • FlowTriever Catheters (available in 4 sizes: 6-10 mm, 11-14 mm, 15-18 mm, and 19-25 mm) The FlowTriever Catheter is inserted through the Triever Catheter and advanced to the thrombus. Self-expanding wireform disks are deployed to engage thrombus by retracting the outer delivery catheter. The FlowTriever Catheter is retracted into the Triever Catheter to capture the targeted thrombus. Additional clot may also be removed by aspiration with the provided 60 cc VacLok Vacuum syringe. After the procedure is complete, the Triever Catheter and FlowTriever Catheter are removed from the patient.

Indications for Use	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 device modification proposed is providing the Large Bore 60 cc Syringe in the sterile package of the Triever16[3]. The same syringe is already provided in the Triever20 (cleared under K182233) used for the same aspiration purpose.
Summary of substantial equivalence	There is no change of intended use or fundamental scientific technology between the proposed and predicate device. The FlowTriever Retrieval/Aspiration System has the same indication for use as the predicate, K183198. <u>Non-Clinical Testing</u> No modifications have been made to the previously cleared Triever16 nor the Large Bore 60 cc Syringe. Design verification for inclusion of the Large Bore 60 cc Syringe with the Triever16 was limited to packaging evaluation after simulated shipping. The risk category, determined during the risk analysis process, was used to assign confidence/reliability percentages in the determination of sample size for design verification testing Accelerated 2-year shelf-life testing for Triever16 and Triever20[4] were leveraged to support a 2-year shelf-life for the Triever16. Clinical testing was not required for the determination of substantial equivalence. Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications. <u>Conclusion</u> The proposed device modifications to the FlowTriever Retrieval/Aspiration System do not change its intended use nor does it change the principles of operation. With consideration of the results of the testing leveraged from K183198, it can be concluded that the proposed FlowTriever Retrieval/Aspiration System is substantially equivalent to the predicate device.

[3] Formerly "16 Fr Aspiration Guide Catheter"

[4] Formerly "20 Fr Aspiration Guide Catheter