September 5, 2019

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

Re: K191710
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: July 9, 2019
Received: July 11, 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)*

K191710

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

Date prepared	June 24, 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 (K191368)
Reference devices	Inari FlowTriever Retrieval/Aspiration System (K173672) Inari FlowTriever Retrieval/Aspiration System (K181325)
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 3 sizes: 16, 20, and 24 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 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 modifications proposed are associated with increasing the Triever Catheter from 20 to 24 Fr. Specifically, these changes are: • Catheter ID increase of 0.048” • Catheter OD increase of 0.046” • Proximal shaft material durometer changed to 72D • 6.4 cm of the proximal shaft material replaced with 55D Pebax • Dilator shaft OD increase of 0.048”
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, K191368. <u>Non-Clinical Testing</u> In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the modified FlowTriever Retrieval/Aspiration System. This testing demonstrated compliance with relevant product specifications. These tests included: • Visual & Dimensional Inspection – Triever24 Catheter/dilator • Guidewire and Sheath Compatibility Verification • Snap Fit, Dilator Luer to Guide Catheter Hemostasis Valve • Leakage Testing – Triever24 Catheter/ Dilator • Vacuum Testing – Triever24 Catheter • Air leakage During Aspiration – Triever24 Catheter • Retraction Force Testing • Kink Radius Testing • Determination of Flowrate • Burst Testing – Triever24 Catheter/Dilator • Clot Burden Removal Validation • Push Button Force • Simulated Use and Tensile Testing – Triever24 Large Bore Syringe • Simulated Use and Tensile Testing – Triever24 Catheter/Dilator • Simulated Use and Torque

	Animal testing confirmed the safety and performance of the Triever24 Catheter. 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 K191368, it can be concluded that the proposed FlowTriever Retrieval/Aspiration System is substantially equivalent to the predicate device.