April 30, 2021

Inari Medical, Inc.
Larry Boucher
Regulatory Affairs Manager
9 Parker, Suite 100
Irvine, California 92618

Re: K211013
Trade/Device Name: FlowTriever Retrieval/Aspiration System, FlowTriever Catheters: Triever 16, Triever 20, Triever 20 Curve, Triever 24
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: April 2, 2021
Received: April 5, 2021

Dear Larry Boucher:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211013

Device Name
FlowTriever Retrieval/Aspiration System, FlowTriever Catheters: Triever 16, Triever 20, Triever 20 Curve, Triever 24

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.

Triever Catheters (Triever 16, Triever 20, Triever 20 Curve, and Triever 24) are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.

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	April 2, 2021
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Larry Boucher Regulatory Affairs Manager
Trade name	FlowTriever Retrieval/Aspiration System, FlowTriever Catheters: Triever 16, Triever 20, Triever 20 Curve, Triever 24
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Secondary Product Code	KRA
Regulatory class	II
Predicate device	Inari FlowTriever Retrieval/Aspiration System (K202345)
Reference Device	Inari FlowTriever Retrieval/Aspiration System (K201541)
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 20 Curved) and 24 Fr) • FlowTriever Catheters (available in 4 sizes: 6-10 mm, 11-14 mm, 15-18 mm, and 19-25 mm) Triever Catheters (Triever 16, Triever 20, Triever 20 Curve, and Triever 24) are inserted and advanced to the thrombus over a pre-placed 0.035" guidewire. After removal of its dilator, thrombus may be removed by aspiration with the provided 60 cc VacLok Vacuum syringe. After the procedure is complete, the Triever Catheter is 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. Triever Catheters (Triever 16, Triever 20, Triever 20 Curve, and Triever 24) are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.

Device modifications	The contraindication for FlowTriever and Triever Catheter has been changed by deleting "chronic clot" from the examples given "…for removal of fibrous, adherent, or calcified material...".
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, K202345. **Non-Clinical Testing** Non-clinical testing was not required to support the change to the contraindications. **Clinical Testing** No clinical data was required to support the change to the contraindications. **Conclusion** Removing "chronic clot" from the example "of fibrous, adherent, or calcified material" of a contraindication for the FlowTriever Retrieval/Aspiration System does not raise new or different questions of safety or and effectiveness. Therefore, the FlowTriever Retrieval/Aspiration System with the modified contraindication is substantially equivalent to the predicate device.