December 18, 2020

Inari Medical
Mr. Eben Gordon
Vice President, RA/QA
9 Parker, Suite 100
Irvine, California 92618

Re: K202345
Trade/Device Name: Triever Catheters
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: November 17, 2020
Received: November 19, 2020

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,

For Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*
K202345

Device Name
Triever Catheters

Indications for Use *(Describe)*
Triever Catheters are 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.

Triever Catheters are intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Triever Catheters 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date prepared	December 7, 2020
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949.600.8433 x114
Contact person	Eben Gordon Vice President, Regulatory Affairs & Quality Assurance
Trade name	Triever Catheters
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II
Predicate device	FlowTriever Retrieval/Aspiration System (K191710)
Reference device	AngioVac Cannula (K190594)
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) Triever Catheters 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	Triever Catheters are 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. Triever Catheters are intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Triever Catheters are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.

Device modification

This submission proposes including clot in transit in the right atrium to the Indications for Use statement for the Triever Catheters.

Summary of substantial equivalence

The Triever Catheters, predicate and reference devices have the same intended use: removal of thrombus and emboli from vessels.

Non-Clinical Testing

Animal testing was performed with the Triever Catheter to evaluate usability of aspiration of the Triever24 catheter when used in the right atrium. While there were some limitations of the study, no adverse events were noted.

Clinical Data

Clinical data was collected and evaluated for 47 patients (out of approximately 7,650 venous thromboembolism procedures performed), in which Triever Catheters were used for treatment in the right atrium. Of these 47 patients treated, 32 patients were treated only in the right atrium with another 15 patients being treated in the right atrium plus either the pulmonary arteries, superior vena cava, or right ventricle.

The Triever24 was used in 61.7% (29/47) of cases, Triever20, 44.7% (21/47), and Triever16, 2.1% (1/47).

One patient with a borderline massive PE with clot in transit, experienced an adverse event resulting in patient death. The patient was given general anesthesia which resulted in progressive deterioration and ultimately death despite successful treatment of the clot-in-transit.

There was no right atrium treatment related cases in which any heart damage, i.e., perforation, valve damage, etc. was noted. The one adverse event, patient death, was attributed to the use of general anesthesia in a tenuous patient. Device effectiveness was substantiated by average clot removal estimated to be almost 90% and Inari Account Managers' assessment of clinician satisfaction based on clot removal performance.

Conclusion

The information provided demonstrates that including clot in transit in the right atrium to the indications for use statement does not raise new or different questions of safety and effectiveness. It can be concluded that the modified Triever Catheter is substantially equivalent to the predicate device.