March 25, 2022

Inari Medical
Ellen Nguyen
Regulatory Affairs Specialist
6001 Oak Canyon, Suite 100
Irvine, California 92618

Re: K220600
Trade/Device Name: Artix Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: February 28, 2022
Received: March 3, 2022

Dear Ellen Nguyen:

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)*

K220600

Device Name
Artix Thrombectomy Device

Indications for Use *(Describe)*
The Artix Thrombectomy Device 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 Artix Thrombectomy Device is intended for use in the peripheral vasculature.

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.

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510(K) SUMMARY

Date prepared	February 28, 2022
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Name of Device	Artix Thrombectomy Device
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 (K201541)
References devices	ReVive PV Thrombectomy Device (K132281) NeVa PV Thrombectomy Device (K201085)
Description	The Artix Thrombectomy Device ("Artix") is a single-use over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature. Artix is inserted through an 8 Fr sheath over a pre-placed 0.014" guidewire and advanced to the thrombus. A self-expanding nitinol element is deployed to engage thrombus by retracting the outer delivery catheter. Artix is then retracted into the sheath to capture the targeted thrombus. Additional clot may be removed by aspiration with a Luer syringe (not provided). After the procedure is complete, the Artix and sheath are removed from the patient.
Indications for Use	The Artix Thrombectomy Device 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 Artix Thrombectomy Device is intended for use in the peripheral vasculature.
Device Modifications	The proposed modifications to the FlowTriever2 Catheter include a modified thrombectomy element, dimensional changes, minor material changes, the addition of a proximal hub, packaging updates, and a contraindication update. These modifications introduce the Artix Thrombectomy Device, a FlowTriever2 catheter variant used for mechanical thrombectomy device in the peripheral vasculature.

	There have been no changes to the Triever or FlowTriever Catheters.
Comparison of Technological Characteristics with the Predicate Device	The proposed modifications do not change the intended use or principles of operation from the predicate device. The modified and predicate device have a similar design and mainly differ in dimensions and element geometry. The information provided in this submission demonstrates that the differences in technological characteristics between the predicate and proposed devices do not raise any new questions of safety and effectiveness. There have been no changes to the Triever or FlowTriever Catheters.
Summary of substantial equivalence	There is no change of intended use or fundamental scientific technology between the proposed device and predicate device. The Artix Thrombectomy Device has the same indication for use as the predicate FlowTriever2 Catheter device, K201541. Non-Clinical Testing In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the Artix Thrombectomy Device. Test results demonstrated that all acceptance criteria were met; therefore, the devices conform to established product specifications. Neither animal testing nor clinical testing were required for the determination of substantial equivalence. **Conclusion** The proposed device modifications to the FlowTriever2 Catheter do not change its intended use, principles of operation, or fundamental design. Non-clinical bench testing supports the Artix Thrombectomy Device's substantial equivalence to the predicate device.