March 2, 2023

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

Re: K223436
Trade/Device Name: Artix AX
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: January 30, 2023
Received: January 31, 2023

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.03.02 16:27:18 -05'00'

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)*

Device Name
Artix AX

Indications for Use *(Describe)*
The Artix AX aspiration catheter 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 AX aspiration catheter 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.

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

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510(K) SUMMARY

Date prepared	March 1, 2023
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 AX
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 (K213402)
References devices	Penumbra Indigo System CAT RX Aspiration Catheter (K163618)
Description	The Artix AX is a single-use, over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The system comprises two catheter lengths, 85 cm and 115 cm, packaged separately. The Artix AX is inserted over a pre-placed guidewire and advanced to the thrombus, which can then be removed via aspiration with the provided 30 mL Large Bore Vacuum Syringe. The Artix MT may also be deployed through the Artix AX to engage thrombus before being retracted through the Artix AX. Additional clot may be removed by aspiration through the Artix AX as necessary. After the procedure is complete, the Artix AX is removed from the patient.
Indications for Use	The Artix AX aspiration catheter 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 AX aspiration catheter is intended for use in the peripheral vasculature.
Device Modifications	The proposed modifications are to the Triever16 component and include dimensional and material changes to the catheter and removal of the dilator. These modifications introduce the Artix AX, a smaller embolectomy catheter used for aspiration thrombectomy in the peripheral vasculature. There have been no changes to the Triever20 Fr/20 Curve and the Triever24 Fr Catheters or the 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 materials.

The Artix AX and Triever16 are both tracked over a pre-placed compatible guidewire. The Artix MT or FlowTriever Catheter can then be deployed through the Artix AX or Triever 16/20/24 Fr catheters respectively to engage and withdraw thrombus. Additional clot can be aspirated through the Artix AX or Triever16 using the provided 30 ml or 60 mL Large Bore Syringe.

Although the predicate and subject devices have different technological characteristics, all leveraged and performed design verification and validation tests confirm that these differences do not raise any new or different questions of safety or effectiveness.

There have been no changes to the Triever20 Fr/20 Curve or the Triever24 Fr Catheters or the 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 AX's indications for use falls within those of the predicate device, K213402: both are indicated for the non-surgical removal of emboli and thrombi from blood vessels and the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. Both are intended for use in the peripheral vasculature. The Triever16 is additionally intended for the treatment of pulmonary embolism and for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.

A tabular comparison of specific technological characteristics between the predicate and subject device is provided below:

Feature	**Artix AX Subject (TBD)**	**Triever16 Predicate (K213402)**
Manufacturer	Inari Medical	Inari Medical
Product code	QEW	QEW
Intended use/Indications for use	The Artix AX aspiration catheter 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 AX aspiration catheter is intended for use in the peripheral vasculature.	The Triever16 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 Triever16 is intended for use in the peripheral vasculature *and for the treatment of pulmonary embolism.* *Triever Catheters are also*

Feature	Artix MT Subject (TBD)	Triever16 Predicate (K213402)
		intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.
Principles of operation	The Artix AX is inserted over a pre-placed guidewire and advanced to the thrombus. The Artix MT can then be deployed through the Artix AX to engage thrombus before being retracted through the Artix AX. Additional clot may be removed by aspiration through the Artix AX with the provided 30 mL Large Bore Vacuum syringe. After the procedure is complete, the Artix AX is removed from the patient.	The Triever16 is inserted over a pre-placed guidewire and advanced to the thrombus. The FlowTriever Catheter can then be deployed through the Triever16 to engage thrombus before being retracted through the Triever16. Additional clot may be removed by aspiration through the Triever16 with the provided 60 mL Large Bore Vacuum syringe. After the procedure is complete, the Triever16 is removed from the patient.
Target vessel	Peripheral vessels $\geq$ 3 mm	Peripheral vessels $\geq$ 6 mm, pulmonary arteries, right heart
Contraindicated vessels	Cerebral, carotid, coronary, pulmonary arteries	Cerebral, carotid, coronary arteries
Guidewire compatibility	Up to 0.035”	Up to 0.035”
Shelf-life	6 months	2 years
Sterilization	EtO	EtO
Single-use	Yes	Yes
Dimensions	OD/ID: 2.8 mm/2.4 mm Working length: 85 cm, 115 cm	OD/ID: 5.3 mm/4.5 mm Working length: 107 cm
Outer Shaft material	Pebax 35D with ProPell, Pebax 45D with ProPell, Pebax 55D with ProPell, Pebax 63D, Pebax 72D	Pebax 35D, Pebax 63D
Inner Shaft Material	Etched PTFE	Etched PTFE
Metal support	Stainless steel coil	Stainless steel coil and braid
Hemostasis valve	Mini Garrote valve	Garrote valve
Tip bevel	30°	No bevel

Biocompatibility

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity

- Material-Mediated Pyrogenicity
- Hemocompatibility (Hemolysis, Complement Activation, Thromboresistance, Platelet and Leukocyte Count, and Partial Thromboplastin Time)

The passing results demonstrate that the subject device and accessories meet biological safety requirements per ISO 10993-1.

Sterilization

The subject device, including its accessories, is sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6}. The subject device has been adopted into a validated sterilization process in accordance with the principles of ISO 11135:2014/Amd 1:2018 (*Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E, Single batch release*) and AAMI TIR 28:2016 (*Product adoption and process equivalence for ethylene oxide sterilization*) without deviations.

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 AX. These tests included:

- Pouch Seal Visual Inspection and Dye Penetration
- Visual & Dimensional Inspection
- Guidewire Compatibility
- Cheater Sheath Compatibility
- Artix MT/BG Compatibility and Simulated Use
- Kink Radius
- Air Leakage During Aspiration
- Leakage Testing
- Vacuum Testing
- Liquid Leakage Under Pressure (300 kPa) Testing
- Determination of Flowrate Through Catheter
- Burst Testing
- Clot Burden Removal Validation
- Simulated Use, Track & Tensile – Catheter
- Simulated Use, Track & Torque – Catheter
- 30 mL Large Bore Syringe Leak Testing
- 30 mL Large Bore Syringe Vacuum Testing
- Simulated Use & Tensile – 30 mL Large Bore Syringe
- Simulated Use & Torque – 30 mL Large Bore Syringe

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications.

Neither animal testing nor clinical testing were required for the determination of substantial equivalence.

Conclusion

The Artix AX has the same intended use/indications for use and principles of operation as the predicate. Performance data shows that the different technological characteristics between the devices do not raise any new or different questions of safety or effectiveness. Non-clinical bench testing supports the Artix AX's substantial equivalence to the predicate device.