August 21, 2026

Inari Medical, Inc.
Tosan Eweka
Sr. Staff Regulatory Affairs Specialist
6001 Oak Canyon
Suite 100
Irvine, California 92618

Re: K262538
Trade/Device Name: Artix™ MT; Artix™ Thin-Walled Sheath
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA, DYB
Dated: July 22, 2026
Received: July 23, 2026

Dear Tosan Eweka:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

KRINA M. PATEL -S

Digitally signed by KRINA M. PATEL -S
Date: 2026.08.21 12:34:03 -04'00'

For,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262538

Please provide the device trade name(s).

Artix™ MT;
Artix™ Thin-Walled Sheath

Please provide your Indications for Use below.

The Artix™ MT 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™ MT thrombectomy device is intended for use in the peripheral vasculature.

The Artix™ Thin-Walled Sheath 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.
• Use as a conduit for endovascular devices.
• Use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel. The funnel provides temporary vascular occlusion during these and other angiographic procedures.
The Artix™ Thin-Walled Sheath is intended for use in the peripheral vasculature.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K262538

510(K) SUMMARY

Date prepared	August 19, 2026
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Tosan Eweka Sr. Staff Regulatory Affairs Specialist
Name of Device	Artix™ MT
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW, KRA
Regulatory class	II
Predicate device	Artix™ MT (K241894)
Description	The Artix MT is a single-use, over-the-wire catheter device used for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The Artix MT is packaged with the following components: • Artix MT (3-6 mm or 4-8 mm) • Cleaning accessory • 1-Way Stopcock The Artix MT is inserted over-the-wire through a compatible sheath (such as the Artix Thin-Walled Sheath) and advanced until its proximal marker band is distal to the target thrombus. The self-expanding element is deployed by retracting the delivery catheter. Thrombus is engaged and removed by retracting the Artix MT into the sheath and out of the patient. Once the procedure is complete, the system is completely withdrawn from the patient.
Indications for Use	The Artix™ MT 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™ MT thrombectomy device is intended for use in the peripheral vasculature.
Device Modifications	Incremental, non-significant modifications made to the Artix MT since clearance was granted under K241894 as follows: addition of alternate suppliers, shelf-life increase, IFU revisions and minor dimensional changes.
Comparison of Technological Characteristics with the Predicate Device	There is no change to the intended use, indications for use, principles of operation, or fundamental scientific technology between Artix MT and the predicate device.

Summary of substantial equivalence	There is no change to the intended use, principles of operation, or fundamental scientific technology between Artix MT and the predicate device. The Artix MT has the same indications for use as the predicate device, K241894. **Non-Clinical Testing** In accordance with the design failure modes and effects analysis, design verification testing was conducted to verify that the modified device continues to meet the design requirements of the product specifications. The following tests were performed on the modified device: • Shelf-life testing • Packaging Testing • Visual and Dimensional Inspections • Simulated Use Testing • Hydrophilic Coating Integrity • Hemostasis • Tensile • Particulate • Liquid Leakage • Burst • Radial Force Neither animal testing nor clinical testing were required for the determination of substantial equivalence. **Conclusion** Artix MT has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports the Artix MT's substantial equivalence to the predicate device.

K262538

510(K) SUMMARY

Date prepared	August 19, 2026
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Tosan Eweka Sr. Staff Regulatory Affairs Specialist
Name of Device	Artix™ Thin-Walled Sheath
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW, DYB, KRA
Regulatory class	II
Predicate device	Artix™ Thin-Walled Sheath (K241894)
Description	The Artix™ Thin-Walled Sheath ("Artix Sheath") is a single-use, over-the-wire system designed to facilitate the insertion and guidance of an intravascular catheter into a selected peripheral blood vessel and act as a conduit for endovascular devices. The Artix Sheath also non-surgically aspirates thromboemboli from selected vessels and is capable of infusion/aspiration of fluids into or from a selected vessel. The Artix Sheath is packaged with the following components: • Artix Thin-Walled Sheath (65 cm or 90 cm) • Sheath Dilator (0.035" guidewire compatibility) • Funnel Catheter and Funnel Catheter Dilator (0.035" guidewire compatibility) • Funnel Loading Tool (2) • Large Bore Syringe, 30 mL The Artix Sheath is inserted over-the-wire and advanced to a desirable position. Any compatible endovascular device, such as the Artix MT, can then be inserted through the Artix Sheath for access into the peripheral vasculature. The provided funnel catheter accessory can also be inserted through the Sheath and deployed to provide flow occlusion of the vessel during the procedure to aid with the system's clot ingestion. Compatible endovascular devices, such as the Artix MT, can be used through the 6 Fr inner diameter of the funnel catheter as well. The provided 30 mL syringe can be used to aspirate clot in the vessel or Sheath and infuse contrast media

	and other fluids as required. Once the procedure is complete, the funnel catheter (if used) is removed prior to withdrawal of the entire system from the patient, and standard 7 Fr closure devices can be used.
Indications for Use	The Artix™ Thin-Walled Sheath 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. • Use as a conduit for endovascular devices. • Use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel. The funnel provides temporary vascular occlusion during these and other angiographic procedures. The Artix™ Thin-Walled Sheath is intended for use in the peripheral vasculature.
Device Modifications	Incremental, non-significant modifications made to the Artix Thin-Walled Sheath since clearance was granted under K241894 as follows: addition of alternate suppliers, shelf-life increase, IFU revisions, minor dimensional changes and addition of alternate funnel loading tool.
Comparison of Technological Characteristics with the Predicate Device	There is no change to the intended use, indications for use, principles of operation, or fundamental scientific technology between Artix Thin-Walled Sheath and the predicate device.
Summary of substantial equivalence	There is no change to the intended use, principles of operation, or fundamental scientific technology between Artix Thin-Walled Sheath and the predicate device. The Artix Thin-Walled Sheath has the same indications for use as the predicate device, K241894. **Non-Clinical Testing** In accordance with the design failure modes and effects analysis, design verification testing was conducted to verify that the modified device continues to meet the design requirements of the product specifications. The following tests were performed on the modified device: • Shelf-life testing • Packaging Testing • Visual and Dimensional Inspections • Simulated Use Testing • Air Leak Testing, Syringe Pullback • Air Leak Testing, Dilator Removal • Hemostasis, Sheath and Dilator • Sheath Burst • Tensile • Hydrophilic Coating Integrity • Lubricity, post-use

	• Vacuum Testing • Particulate • Sheath and Funnel Catheter Aspirational Flow Rate • Kink Torque • Continuous Bend Neither animal testing nor clinical testing were required for the determination of substantial equivalence. **Conclusion** Artix Thin-Walled Sheath has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports the Thin-Walled Sheath's substantial equivalence to the predicate device.