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

Re: K241894
Trade/Device Name: Artix™ MT; Artix™ Thin-Walled Thrombectomy Sheath
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA, DQY
Dated: June 28, 2024
Received: June 28, 2024

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.10.15 14:40:21 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241894

Device Name
Artix™ MT;
Artix™ Thin-Walled Sheath

Indications for Use *(Describe)*
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.

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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"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	October 10, 2024
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Ellen Nguyen Senior Regulatory Affairs Specialist
Name of Device	Artix™ MT
Product code(s)	QEW; KRA
Regulation(s)	21 CFR 870.5150 Embolectomy catheter
Regulatory class	II
Predicate device	Inari Medical, Artix Thrombectomy Device (K220600) This device has not been subject to a design-related recall.
Reference devices	Surmodics, Pounce LP Thrombectomy System (K231022) Vascular Medcure, CAPERE Thrombectomy System (K203476) Inari Medical, FlowTriever2 Catheter (K201541) Inari Medical, InThrill Thrombectomy System (K223613)
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.
Comparison of Technological	The Artix MT and Artix Thrombectomy Device are both delivered over a previously placed 0.014" guidewire through a compatible sheath, such as the Artix Thin-

Characteristics with the Predicate Device

Walled Sheath, to a location proximal of the target thrombus. Under fluoroscopic guidance, both devices are advanced until the proximal marker band is distal to and/or within the clot. The delivery catheter is retracted to allow the nitinol element to expand and capture thrombus. The entire device is manually retracted inside the sheath and out of the patient to remove the thrombus.

Changes to the predicate device that have led to the submission of this new 510(k) are a modification of the element geometry, catheter length increase, material changes, an update to the packaging dispenser card configuration, and the addition of a cleaning accessory. These changes result in characteristics that are similar to those of the predicate and reference devices.

The proposed modifications do not change the intended use or principles of operation from the predicate device. The modified and predicate devices have similar designs. All leveraged and performed design verification and validation tests confirm that the differences between the devices do not raise any new or different questions of safety or effectiveness.

Summary of substantial equivalence

There is no change of intended use or fundamental scientific technology between the proposed device and predicate device. The indications for use remain the same.

Device	Artix™ MT Proposed (TBD)	Artix™ Thrombectomy Device Predicate (K220600)
Manufacturer	Inari Medical, Inc.	Inari Medical, Inc.
Regulations	21 CFR 870.5150 Embolectomy catheter 21 CFR 870.1210 Continuous flush catheter	21 CFR 870.5150 Embolectomy catheter 21 CFR 870.1210 Continuous flush catheter
Product code	QEW, KRA	QEW, KRA
Intended use/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.	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.
Contraindications	• Not intended for use in the pulmonary, cerebral, carotid, or coronary arteries. • Not intended for use in endarterectomy procedures or vessel dilation.	• Not intended for use in the pulmonary, cerebral, carotid, or coronary arteries. • Not intended for use in endarterectomy procedures or vessel dilation.

	• Not indicated for the removal of fibrous, adherent, or calcified material (e.g., atherosclerotic plaque). • Not intended for use in vessels < 3 mm. • Not intended for use with power injectors.	• Not indicated for the removal of fibrous, adherent, or calcified material (e.g., atherosclerotic plaque). • Not intended for use in vessels < 3 mm. • Not intended for use with power injectors.
Principles of operation	A compatible sheath is placed over a guidewire to a location proximal of the target thrombus. The Artix MT can be used for mechanical thrombectomy by advancing and deploying directly through the sheath.	A compatible sheath is placed over a guidewire to a location proximal of the target thrombus. The Artix Thrombectomy Device can be used for mechanical thrombectomy by advancing and deploying directly through the sheath.
Intended patient population	Same	Adults undergoing interventional procedures
Target vessel	Same	Peripheral vasculature
Sterile	Same	SAL 10^{-6}, EO
Device and packaging materials	Same	Biocompatible, commonly used materials for medical devices
Shelf-life	6 months	2 years*
Single use	Yes	Yes
Vessel diameters treated	3-6 mm 4-8 mm	3-8 mm
Device dimensions	Same with longer total lengths for the new models and different element lengths/diameters	Appropriately sized for the target vessel treatment range
Radiopaque element(s)	Platinum wire Pebax, Tungsten marker band	Platinum-iridium marker band
Guidewire compatibility	Same	0.014”
Accessories provided	Stopcock Cleaning accessory	Stopcock

Biocompatibility

The following biocompatibility tests were completed for the subject devices:

- Cytotoxicity
- Sensitization

- Intracutaneous Reactivity
- Material-Mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility (Hemolysis)
- Genotoxicity

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

Sterilization

The subject device is sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6} using a validated sterilization process in accordance with the principles of ISO 11135:2014/Amd 1:2018 and AAMI TIR 28:2016.

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 MT. These tests included:

- Packaging Testing
- Visual and Dimensional Inspections
- Simulated Use Testing
- Hemostasis
- Tensile
- Particulate
- Liquid Leakage
- Burst
- Corrosion
- Radiopacity
- Radial Force
- Chronic Clot Analog

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

Conclusion

The Artix™ MT has the same intended use/indications for use and principles of operation as its predicate. The testing provided supports the Artix MT's substantial equivalence to the predicate device.

510(K) SUMMARY

Date prepared	October 10, 2024
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Ellen Nguyen Senior Regulatory Affairs Specialist
Name of Device	Artix™ Thin-Walled Sheath
Product code(s)	QEW; DQY
Regulation	21 CFR 870.5150 Embolectomy catheter
Regulatory class	II
Predicate device	Inari Medical, Artix BG (K230912) This device has not been subject to a design-related recall.
Reference device(s)	Surmodics, Pounce Thrombectomy System (K231022) Capture Vascular, MegaVac Mechanical Thrombectomy System (K171493) Inari Medical, ClotTriever Sheath (K233815)

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.

Comparison of Technological Characteristics with the Predicate Device

The Artix Thin-Walled Sheath and Artix BG are both tracked over a pre-placed compatible guidewire. Compatible endovascular devices, such as the Artix MT, can then be deployed through the sheath to engage and withdraw thrombus. The funnel and balloon respectively provide flow occlusion of the vessel during the procedure to aid with the system's clot ingestion. Additional clot can be aspirated through the Artix Sheath or Artix BG using the provided 30 mL Large Bore Syringe.

Changes to the predicate device that have led to the submission of this new 510(k) are a change of the occlusive element from a balloon to a funnel and the inclusion of associated accessories, a reduction of the sheath's outer profile, a decrease to the working length of the longer model, material changes, and an updated packaging dispenser card configuration. These changes result in characteristics that are similar to those of the predicate and reference devices.

Although the modified and predicate devices have different designs, the proposed modifications do not change the intended use or principles of operation from the predicate device. All leveraged and performed design verification and validation tests confirm that the differences do not raise any new or different questions of safety or effectiveness.

Summary of substantial equivalence

There is no change of intended use or fundamental scientific technology between the proposed device and predicate device. Aside from some clarification updates, the indications for use remain the same.

Device	Artix™ Thin-Walled Sheath - Proposed (TBD)	Artix™ BG - Predicate (K230912)
Manufacturer	Inari Medical, Inc.	Inari Medical, Inc.
Regulations	21 CFR 870.5150 Embolectomy catheter 21 CFR 870.1250 Percutaneous catheter	21 CFR 870.5150 Embolectomy catheter 21 CFR 870.1250 Percutaneous catheter
Product code	QEW, DQY	QEW, DQY
Intended use/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	The Artix BG balloon thrombectomy sheath is indicated for: • The non-surgical aspiration 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.	and other fluids into or from a blood vessel. • Use as a conduit for retrieval devices. • Use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Artix BG balloon thrombectomy sheath is intended for use in the peripheral vasculature.
Principles of operation	After the target vessel is accessed and dilated, the Artix Thin-Walled Sheath is inserted into the vessel over a guidewire. Once the Sheath is in position, the dilator is removed, and all compatible endovascular devices, such as the Artix MT, can 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 clot ingestion. 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.	After the target vessel is accessed and dilated, the Artix BG is inserted into the vessel over a guidewire. Once the Artix BG is in position, the dilator is removed, and all compatible catheter devices, such as the Artix Thrombectomy Device (K220600), can be inserted through the Artix BG for access into the peripheral vasculature. The sheath's balloon can also be inflated using a 1 mL syringe to provide flow occlusion of the vessel during the procedure. 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.
Intended patient population	Same	Adults undergoing interventional procedures
Target vessel	Same	Peripheral vasculature
Sterile	Same	SAL 10^{-6}, EO
Device and packaging materials	Same	Biocompatible, commonly used materials for medical devices
Device dimensions	Same with decreased OD profile and length increase of the longer model	Appropriately sized for the introduction of interventional devices into the target vessel
Shelf-life	6 months	2 years*
Single use	Yes	Yes

Marker band	Pebax, Tungsten	Platinum-Iridium
Guidewire compatibility	0.035”	0.014” or 0.035”
Accessories provided	Dilators (2), funnel catheter, funnel loading tool (2), large-bore syringe	Dilators (2), balloon inflation syringe, large-bore syringe

Biocompatibility

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Intracutaneous Reactivity
- Material-Mediated Pyrogenicity
- Sensitization
- Acute Systemic Toxicity
- Hemocompatibility (Hemolysis)
- Genotoxicity

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

Sterilization

The subject device and its accessories are sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6} using a validated sterilization process in accordance with the principles of ISO 11135:2014/Amd 1:2018 and AAMI TIR 28:2016.

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 Thin-Walled Sheath. These tests included:

- Packaging Testing
- Visual and Dimensional Inspections
- Simulated Use Testing
- Air Leak Testing, Syringe Pullback
- Hemostasis, Sheath and Dilator
- Clot Burden Removal
- Sheath Burst
- Air Leak Testing, Dilator Removal
- Tensile
- Dye Staining
- Lubricity, Post-Use
- Vacuum Testing
- Particulate
- Sheath Aspirational Flow Rate
- Kink
- Radiopacity
- Torque

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

Conclusion

The Artix™ Thin-Walled Sheath has the same intended use and principles of operation as the predicate device. The testing provided supports the Artix Thin-Walled Sheath's substantial equivalence to the predicate devices.