December 11, 2023

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

Re: K223000
Trade/Device Name: Artix BG
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, DQY
Dated: December 9, 2022
Received: December 9, 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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2023.01.11 09:19:48 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
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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)*
K223000

Device Name
Artix BG

Indications for Use *(Describe)*
The Artix BG balloon thrombectomy sheath is indicated for:

• 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.
• Use as a conduit for retrieval devices.
• 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.

The Artix BG balloon thrombectomy 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.

510(K) SUMMARY

Date prepared	January 10, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Trade name	Artix BG
Common name	Balloon thrombectomy sheath
Regulation name	Percutaneous catheter
Classification number	21 CFR 870.1250
Product code	QEW
Secondary product code	DQY
Regulatory class	II
Predicate device	Inari Medical, ClotTriever Thrombectomy System (K212632)
Reference device	Inari Medical, Artix Balloon Guiding Sheath (K221846)
Description	The Artix BG 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 retrieval devices. A compliant balloon mounted at the sheath's distal tip provides temporary vascular occlusion during angiographic and interventional procedures. The Artix BG also non-surgically aspirates thromboemboli from selected vessels and is capable of infusion/aspiration of fluids into or from a selected vessel. The Artix BG is packaged with the following components: • Artix BG balloon thrombectomy sheath (8 Fr, 65 cm or 105 cm) • 8 Fr Introducer Dilator (0.014" and 0.035" guidewire compatibility) • Balloon Inflation Syringe, 1 mL • Large Bore Syringe, 30 mL • 3-way Stopcock
Indications for Use	The Artix BG balloon thrombectomy sheath is indicated for: • 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. • Use as a conduit for retrieval devices. • 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.

The Artix BG balloon thrombectomy sheath is intended for use in the peripheral vasculature.

Summary of substantial equivalence

The predicate ClotTriever Thrombectomy System is indicated for "The non-surgical removal of emboli and thrombi from blood vessels and injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel." The Artix BG's expanded indications for use are identical. Both devices are intended for use in the peripheral vasculature, with the only difference being that the predicate device is also intended for the treatment of deep vein thrombosis (DVT).

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

Feature	Artix BG - Subject Device	ClotTriever Thrombectomy System - Predicate (K212632)	Artix Balloon Guiding Sheath – Reference Device (K221846)
Manufacturer	Inari Medical	Inari Medical	Inari Medical
Product code	QEW, DQY	QEW	DQY
Intended use/Indications for use	The Artix BG balloon thrombectomy sheath is indicated for: • 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. • Use as a conduit for retrieval devices. • The non-surgical aspiration of thrombi and emboli from blood vessels. • Infusion, injection, and/or aspiration of contrast media or other fluid into or from a blood vessel. The Artix BG balloon thrombectomy sheath is intended for use in the peripheral vasculature.	The ClotTriever Thrombectomy System is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Infusion, injection, and/or aspiration of contrast media or other fluid into or from a blood vessel. The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).	The Artix Balloon Guiding Sheath is indicated for 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 Balloon Guiding Sheath is also indicated for use as a conduit for retrieval devices. The Artix Balloon Guiding Sheath is intended for use in the peripheral vasculature.

Feature	Artix BG - Subject Device	ClotTriever Thrombectomy System - Predicate (K212632)	Artix Balloon Guiding Sheath – Reference Device (K221846)
Device description	The Artix BG is comprised of a single through lumen shaft with four (4) embedded lumens for balloon inflation and deflation, a proximal integrated hemostasis valve to minimize blood loss, a stopcock with flush port, and a balloon port. To assist with insertion of the sheath into the vasculature, a hydrophilic coating covers a portion of the distal sheath shaft. The distal tip of the sheath shaft contains two (2) radiopaque marker bands to aid with angiographic visualization: The distal marker indicates the location of the sheath's tip, while the proximal marker band marks the location of a compliant balloon mounted at the distal end. The balloon provides temporary vascular occlusion during angiographic and interventional procedures.	The ClotTriever Thrombectomy System consists of ClotTriever 13 Fr and 16 Fr Sheaths ("Sheath") and the ClotTriever/ClotTriever Bold Catheter ("Catheter"), each packaged separately. The sheath is an introducer sheath with a distal self-expanding funnel, aspiration port, and proximal hub. A dilator is provided to aid insertion and positioning of the sheath. Other provided accessories include a 60 cc large bore syringe that provides a vacuum source and collects aspirated contents. Radiopaque markers aid sheath positioning under fluoroscopic visualization. The dilator tip is radiopaque, and there is a radiopaque marker band near the distal end of the sheath.	The Artix Balloon Guiding Sheath is comprised of a single through lumen shaft with four (4) embedded lumens for balloon inflation and deflation, a proximal integrated hemostasis valve to minimize blood loss, a stopcock with flush port, and a balloon port. To assist with insertion of the sheath into the vasculature, a hydrophilic coating covers a portion of the distal sheath shaft. The distal tip of the sheath shaft contains two (2) radiopaque marker bands to aid with angiographic visualization: The distal marker indicates the location of the sheath's tip, while the proximal marker band marks the location of a compliant balloon mounted at the distal end. The balloon provides temporary vascular occlusion during angiographic and interventional procedures.
Principles of operation	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 MT (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	After the target vessel is accessed and dilated, the ClotTriever Sheath is inserted into the vessel over a guidewire. The ClotTriever/ClotTriever Bold Catheter can then be advanced through the sheath and beyond the clot. The self-expanding braided nitinol wire net is deployed. The expanded net cores, separates, and entraps thrombus from the vessel as it is being drawn	After the target vessel is accessed and dilated, the Artix Balloon Guiding Sheath is inserted into the vessel over a guidewire. Once the Artix Sheath is in position, the dilator is removed, and all compatible catheter devices can be inserted through the Artix Sheath for access into the peripheral vasculature. The sheath's balloon can

Feature	Artix BG - Subject Device	ClotTriever Thrombectomy System - Predicate (K212632)	Artix Balloon Guiding Sheath – Reference Device (K221846)
	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.	to the funnel opening of the ClotTriever Sheath. The net is collapsed and pulled into and through the ClotTriever Sheath with the entrapped clot. A 60 cc syringe is provided for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.	also be inflated using a 1 mL syringe to provide flow occlusion of the vessel during the procedure.
Intended patient population	Adults undergoing interventional procedures	Adults undergoing interventional procedures	Adults undergoing interventional procedures
Target vessel	Peripheral vasculature	Peripheral vasculature	Peripheral vasculature
Placement duration	< 24 hours	< 24 hours	< 24 hours
Guidewire compatibility	0.014" or 0.035"	0.035"	0.014" or 0.035"
Sterilization	EtO	EtO	EtO
Single-use	Yes	Yes	Yes

Summary of substantial equivalence

Biocompatibility

This submission proposes no changes to the device materials. Therefore, the previous passing results demonstrating that the Artix BG (K221846) and accessories meet biological safety requirements per ISO 10993-1 are still applicable.

Sterilization

The subject device, including its accessories, 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 (*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*). This submission proposes no changes to the device design or materials. Therefore, the previous sterilization process per K221846 remains applicable.

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 BG to the ClotTriever Thrombectomy System. These tests included:

- Sheath Visual & Dimensional
- Simulated Use Cycling
- Sheath Aspirational Flowrate
- Clot Burden Removal

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 nonclinical tests demonstrate the Artix BG's substantial equivalence to the ClotTriever Thrombectomy System.