July 11, 2022

Inari Medical
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K221846
Trade/Device Name: Artix Ballon Guiding Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 23, 2022
Received: June 24, 2022

Dear Prithul Bom:

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,

For
Misti Malone
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)*
K221846

Device Name
Artix Balloon Guiding Sheath

Indications for Use *(Describe)*
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.

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	June 9, 2022
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 Balloon Guiding Sheath
Common name	Balloon guiding sheath
Regulation name	Percutaneous catheter
Classification number	21 CFR 870.1250
Product code	DQY
Regulatory class	II
Predicate device	Concentric Medical, 8F FlowGate2 Balloon Guide Catheter (K153729)
Reference device	Medtronic Vascular, Inc., Sentrant Introducer Sheath with Hydrophilic Coating (K171866)
Description	The Artix Balloon Guiding 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 retrieval devices. A compliant balloon mounted at the sheath's distal tip provides temporary vascular occlusion during angiographic procedures. The Artix Balloon Guiding Sheath is packaged with the following components: • Artix Balloon Guiding Sheath (8 Fr, 65 cm or 105 cm) • Two 8 Fr Introducer Dilators (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 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.

Summary of substantial equivalence

The Artix Balloon Guiding Sheath and predicate device have the same indications for use statement: both are indicated for vascular access, facilitating the insertion and guidance of intravascular devices into selected blood vessels in the peripheral vasculature, providing temporary vessel occlusion during angiographic procedures, and to act as a conduit for retrieval devices. Unlike the predicate device, the Artix Balloon Guiding Sheath is not indicated for use in the neurovasculature.

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

Feature	Subject Device	8F FlowGate2 Balloon Guide Catheter - Predicate (K153729)
Manufacturer	Inari Medical	Concentric Medical
Product code	DQY	DQY
Intended use/Indications for use	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.	FlowGate2 Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular device into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.
Device description	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	The FlowGate2 Balloon Guide Catheters are coaxial-lumen, braid-reinforced, variable stiffness catheters designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation, and aspiration.

Feature	Subject Device	8F FlowGate2 Balloon Guide Catheter - Predicate (K153729)
	at the distal end. The balloon provides temporary vascular occlusion during angiographic procedures.	Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label.
Principles of operation	After the target vessel is accessed and dilated, the Artix Balloon Guiding Sheath is inserted into the vessel over a guidewire. Once the Artix Balloon Guiding Sheath is in position, the dilator is removed, and all compatible catheter devices can be inserted through the Artix Balloon Guiding Sheath 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.	After the target vessel is accessed and dilated, the 8F FlowGate2 Balloon Guide Catheter is inserted into the vessel. The dilator can then be removed to allow compatible working devices to be inserted through the catheter. The balloon can also be inflated to provide flow occlusion of the vessel.
Intended patient population	Adults undergoing interventional procedures	Adults undergoing interventional procedures
Target vessel	Peripheral vasculature	Peripheral and neurovasculature
Placement duration	< 24 hours	< 24 hours
Guidewire compatibility	0.014" or 0.035"	0.035"
Sterilization	EtO	EtO
Single-use	Yes	Yes
Dimensions		
Sheath dimensions	OD/ID: 11 Fr/8 Fr Effective Lengths: 105 cm and 65 cm	OD/ID: 8 Fr/6.4 Fr Effective Lengths: 100 cm and 95 cm
Balloon dimensions	Ø 11 mm maximum OD Length: 10 mm	Ø 10 mm maximum OD Length: 10 mm
Materials		
Shaft material	Pebax 4033	Proximal: Pebax 7233 Distal: Pebax 6333 Tip: Pebax 2533, Pebax 3533, BaSO4
Coating	Hydrophilic, biocompatible	None
Balloon	Chronoprene 40A thermoplastic elastomer	NuSil MED 4025 silicone elastomer

Feature	Subject Device	8F FlowGate2 Balloon Guide Catheter - Predicate (K153729)
Liner	Etched PTFE	Etched PTFE
Shaft support	304V Stainless Steel braid and coil	304V Stainless Steel braid
Strain relief	Pellethane 2363-80A Pantone 2104C PMS	Pebax 4033, White Polyolefin, White
Marker band	Platinum-iridium	Platinum-iridium
Accessories		
Accessories provided	Dilators (2), balloon inflation syringe, large bore syringe, 3-way stopcock, hemostasis valve and side port lumen (integrated into sheath shaft)	Dilator, rotating hemostasis valve, Tuohy-Borst valve with sideport, Peel-Away Sheaths, Luer-activated valve, Extension Tubing
Dilator length	115 cm, 72 cm (working length)	123 cm (working length)
Dilator material	Shaft: LDPE/HDPE Hub: HDPE Cap: ABS, 4% Cool Gray	Shaft: Pebax, BaSO4 Hub: White polycarbonate
Dilator OD	0.110 in.	Distal: 0.072 in. Proximal: 0.078 in.

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 Balloon Guiding Sheath to the FlowGate2 Balloon Guide Catheter. These tests included:

- Pouch Seal Peel Test
- Pouch Seal Inspection and Pouch Dye Penetration
- Packaging Retention
- Visual and Dimensional Inspections - Sheath
- Dimensional Inspections – Sheath Inner Diameter
- Visual and Dimensional Inspections – Dilator
- Dimensional Inspections – Dilator Outer Diameter
- Guidewire Compatibility, Dilator
- Visual – Sheath and Dilator
- Dimensional Inspections – Sheath Working Length
- Simulated Use Cycling
- Cap Locking
- Device Retrieval Testing
- Device Priming
- Air Leak Testing, Syringe Pullback
- Fluid Leak Testing, Sheath
- Fluid Leak Testing, Dilator
- Air Leak Testing, Dilator Removal
- 30 mL Large Bore Syringe Vacuum
- Balloon Fatigue Test
- Sheath and Dilator Kink Radius
- Dye Staining, Post-Use
- Vacuum Testing
- Dilator Hub to Cap Tensile
- 30 mL Large Bore Syringe, Tip Adapter to Barrel Tensile
- Unlocking Cap, Torque
- Insertion Force, Dilator Through Sheath
- Flushing Side Port to Hemostasis Valve Assembly and Inflation Hub Tensile
- Hemostasis Valve Assembly to Sheath Shaft and Dilator Tensile
- Engaged Housing, Cap Axial Detachment
- Balloon Diameter, Inflated
- Barbed Luer to Inflation Hub Torque
- Balloon Burst Volume
- Retraction Force, Dilator from Sheath
- Lubricity, Post-Use
- Particulate Matter Determination
- Torque, Sheath and Dilator
- Balloon Inflation Volume to Balloon Diameter
- Balloon Deflation Time

- Sheath Compatibility with Intravascular Catheter and Diagnostic Catheter in Model
- Sheath Kink to Failure
- Sheath Torque to Failure
- Sheath Tip Tensile
- Sheath Burst
- Manual Syringe Injection Flow Rate and Max Pressure

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 demonstrated that the device is substantially equivalent to the predicate device.