May 2, 2023

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

Re: K230912
Trade/Device Name: Artix BG
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, DQY
Dated: March 31, 2023
Received: March 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: 2023.05.02 08:47:10 -04'00'

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.

Submission Number *(if known)*

K230912

Device Name

Artix BG

Indications for Use *(Describe)*

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 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.

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	March 31, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Name of Device	Artix BG
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Secondary product code	DQY
Regulatory class	II
Predicate device	Inari Medical, Artix BG (K223000) This device has not been subject to a design-related recall.
Description	The Artix BG is a single-use, over-the-wire system designed to aspirate thrombi and emboli from the peripheral vasculature, facilitate the insertion and guidance of an intravascular catheter into selected peripheral blood vessels, 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 is also 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: • 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 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.

Device Modifications	The proposed modification to the Artix BG is the addition of two alternate suppliers for the device's PTFE liner.
Comparison of Technological Characteristics with the Predicate Device	The proposed device and predicate device have the same design and materials of construction. The modification does not change the basic design, the indications for use, or the principles of operation from the predicate device.
Summary of substantial equivalence	There is no change of intended use, design, fundamental scientific technology, or principles of operation between the proposed device and predicate device. The Artix BG has the same indication for use as the predicate device, K223000. **Biocompatibility** The following biocompatibility tests were completed for the subject device: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material-Mediated Pyrogenicity • Hemocompatibility (Hemolysis) 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} 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** As there were no proposed design changes, previous performance test results that demonstrated that all acceptance criteria were met continue to apply; 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 BG has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports the Artix BG's substantial equivalence to the predicate device.