April 1, 2022

Inari Medical, Inc.
Kit Cariquitan
Vice President, Regulatory Affairs
9 Parker, Suite 100
Irvine, California 92618

Re: K212392
Trade/Device Name: Intri24 Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 25, 2022
Received: February 28, 2022

Dear Kit Cariquitan:

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,

Finn Donaldson
Assistant Director (Acting)
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)*
K212392

Device Name
Intri24 Sheath

Indications for Use *(Describe)*
The Intri24 Sheath is indicated to provide a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.

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.

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510(K) SUMMARY

Date prepared	July 29, 2021
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877-923-4747
Contact person	Kit Cariquitan Vice President, Regulatory Affairs & Quality Assurance
Name of Device	Intri24 Sheath
Common name	Introducer Sheath
Regulation name	Catheter Introducer
Classification number	21 CFR 870.1340
Product code	DYB
Regulatory class	II
Predicate device	W.L. Gore DrySeal Sheath with Hydrophilic Coating (K121234) This product has not been subject to a design-related recall.
Reference device	ClotTriever Thrombectomy System (K180329)
Description	The Intri24 Sheath is a single-use, sterile medical device for use in the peripheral vasculature. The Intri24 Sheath is an introducer sheath consisting of a short single lumen catheter with a hydrophilic coating, proximal hemostasis valve, and stopcock with flush port. A radiopaque marker is positioned near the distal tip of the sheath to aid with fluoroscopic visualization. The Intri24 Dilator is compatible with a 0.035" guidewire and has a tapered leading edge which aids insertion and positioning of the Intri24 Sheath.
Indications for Use	The Intri24 Sheath is indicated to provide a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.

Comparison of Technological Characteristics with the Predicate Device	The indications for use and principles of operation of the Intri24 Sheath and the predicate device are substantially the same. Both devices act as conduit for the insertion and removal of endovascular devices. The design and materials of construction of both devices is also substantially the same. The shafts of both devices contain a hydrophilic coating to reduce the insertion force through skin and tissue. Both sheaths also include an appropriately sized dilator (0.035 in guidewire compatible) with a tapered tip to aid in dilation of the target vessel when inserting the sheath. The Intri24 Sheath contains a user-actuated hemostasis valve identical to that used on the ClotTriever catheter and sheath (K180329). The hemostasis valve on the Intri24 Sheath allows for inserting or withdrawing endovascular devices through the sheath. The user actuated hemostasis valve is operated by spring-loaded push buttons. The W.L. Gore DrySeal hemostasis valve contains an inflatable ring which closes when saline is injected and opens when saline is withdrawn from the ring.
Summary of substantial equivalence	The Intri24 Sheath's design, materials, mechanism of action, and performance specifications are substantially equivalent to the predicate device. <u>Non-Clinical Testing</u> In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the Intri24 Sheath. This testing demonstrated compliance with relevant product specifications. These tests included: • Visual and Dimensional Inspection • Dye Staining • Lubricity and Durability • Guidewire Compatibility • Insertion Force • Locking Cap Force • Kink Radius and Dilator Retraction Force • Leak Testing • Simulated Use • Flowrate Testing • Vacuum Testing • Sheath Burst • Push-Button Force • Tensile, Compression, and Torque Testing • Placement Resistance Testing • In Vivo Functional Testing/Radiopacity Verification

	• Pouch Seal Visual Inspection and Dye Penetration • Pouch, Peel, Seal Strength • Sterilization Validation <u>Biocompatibility Testing</u> The following biocompatibility tests were conducted in accordance with ISO 10993-1:2018 and successfully passed: • L-929 MEM Elution • Kligman Maximization • Intracutaneous Injection • Systemic Injection • Pyrogen • Blood Hemolysis • Complement Activation • Thromboresistance • Platelet and Leukocyte Count • Partial Thromboplastin Time Animal and clinical testing were not required for the determination of substantial equivalence. Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications. **<u>Conclusion</u>** Non-clinical testing demonstrated that the Intri24 Sheath is substantially equivalent to the W.L. Gore DrySeal Sheath with Hydrophilic Coating with respect to design, materials, function, and intended use.