December 12, 2023

Kaitlyn Weinkauf
Sr. Regulatory Affairs Specialist
6001 Oak Canyon, Suite 100
Irvine, California 92618

Re: K233646
Trade/Device Name: Intri24 Introducer Sheath (52-101)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 13, 2023
Received: November 14, 2023

Dear Kaitlyn Weinkauf:

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.

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2023.12.12 11:02:47 -05'00'

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)*
K233646

Device Name
Intri24 Introducer Sheath (52-101)

Indications for Use *(Describe)*
The Intri24 Introducer 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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	November 13, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Name of Device	Intri24 Introducer Sheath (52-101)
Common name	Catheter Introducer
Regulation name	Catheter Introducer
Classification number	21 CFR 870.1340
Product code	DYB
Regulatory class	II
Predicate device	Inari Medical, Intri24 Introducer Sheath (K212392)
Description	The Intri24 Introducer Sheath is a single-use over-the-wire system intended for use in vessels > 9 mm and is a conduit for the insertion of diagnostic or endovascular devices into the peripheral vasculature. The Intri24 Introducer Sheath consists of a Sheath and Dilator. The Sheath is comprised of a single lumen catheter with a hydrophilic coating, a 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 Dilator is 0.035" guidewire compatible and attaches to the hemostasis valve on the Sheath. The Dilator has a tapered edge to aid in the dilation of the target vessel for insertion and positioning of the Sheath.
Indications for Use	The Intri24 Introducer Sheath is indicated to provide a conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions.
Device Modifications	Changes were made to the sheath to 1) extend the PTFE liner, 2) make minor dimensional and design changes to the valve and, 3) add suppliers of the PTFE liner.
Comparison of Technological Characteristics with the Predicate Device	There is no change to the intended use, indications for use, technological characteristics, principles of operation, or fundamental scientific technology between the proposed Intri24 Introducer Sheath and the predicate device.
Summary of substantial equivalence	There is no change to the intended use, technological characteristics, principles of operation, or fundamental scientific technology between the proposed Intri24 Introducer Sheath and the predicate device. The Intri24 Introducer Sheath has the same indications for use as the predicate device, K212392.

Biocompatibility

The following biocompatibility tests were completed to satisfy ISO 10993-1 requirements for the subject device:

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

The passing results demonstrate that the subject device meets the 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, design verification testing was conducted to verify that the modified device continues to meet the design requirements of the product specifications.

The following tests were performed on the modified device:

- Sheath Visual Inspection
- Sheath Dimensional Inspection
- Sheath/Dilator Kink Radius
- Simulated Use, Track, and Rotation
- Simulated Use, Track, and Triever24
- Simulated Use, Track, and FlowTriever Catheter XL Disks
- Tensile Testing – Sheath Distal Tip Fuse to Shaft
- Tensile Testing – Sheath Hemostasis Valve to Proximal Shaft
- Placement Resistance Testing, Sheath Hub
- Fluid Leak and Fluid Vacuum Test
- Locking Cap Force and Unlocking Cap Torque
- Low Pressure Fluid Leakage Testing, Sheath
- High Pressure Fluid Leakage Testing, Sheath with Blood Analog
- Air Leakage Testing, Dilator Removal
- Air Leakage Testing, Syringe Pullback
- Vacuum Testing
- Sheath Burst

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

	Conclusion The Intri24 Introducer Sheath has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports the Intri24 Introducer Sheath's substantial equivalence to the predicate device.