September 27, 2023

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

Re: K231108
Trade/Device Name: Talon Transseptal Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 22, 2023
Received: August 22, 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,

Rachel E. Neubrander -S

Rachel Neubrander, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*
K231108

Device Name
Talon Transeptal Sheath

Indications for Use *(Describe)*
The Talon Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture.

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	September 22, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Ellen Nguyen Sr. Regulatory Affairs Specialist
Trade name	Talon Transseptal Sheath
Common name	Catheter introducer
Regulation name	Catheter introducer
Classification number	21 CFR 870.1340
Product code	DYB
Regulatory class	II
Predicate device(s)	Baylis Medical, VersaCross Transseptal Sheath (K183655)
Reference device(s)	Cook, Extra Large Check-Flo Introducer (K203670) Inari Medical, Triever24 (K213402)
Description	The Talon Transseptal Sheath ("Sheath") provides a conduit for catheterization and angiography of specific heart chambers and locations. It consists of a single lumen catheter with a proximal hemostasis valve and stopcock with flush port. A radiopaque marker is positioned near the distal tip to aid with fluoroscopic visualization. The Sheath is packaged with a dilator and two 60 cc syringes. The dilator is compatible with a 0.035" guidewire and has a tapered tip which aids insertion and positioning of the Sheath. The dilator attaches to the Sheath hemostasis valve, and a Y-connector with hemostasis valve connects to the dilator luer connector. A quick-release syringe is provided to connect to the Sheath sideport, and a standard VacLok syringe is provided to connect to the Sheath flush port and dilator connector.
Indications for Use	The Talon Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture.

Summary of substantial equivalence

A tabular comparison of the predicate and subject devices is provided below:

	Subject Device Talon Transseptal Sheath	***Primary Predicate*** VersaCross Transseptal Sheath
K Number	TBD	K183655
Manufacturer	Inari Medical, Inc.	Baylis Medical Company, Inc.
Regulations	21 CFR 870.1340 Introducer, catheter	21 CFR 870.1340 Introducer, catheter
Product Code	DYB	DYB
Indications for Use	The Talon Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture.	The VersaCross Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture.
Target Vessel	Heart (all chambers)	Heart (all chambers)
Sterility	SAL 10^{-6}, EO	SAL 10^{-6}, EO
Shelf-life	6 months	Unknown
Guidewire compatibility	0.035”	0.035”
Sheath Dimensions	OD: 23 Fr ID: 20.7 Fr Length: 80 cm	OD: 10.5 Fr ID: 8.5 Fr Length: 63 cm, 81 cm
Shaft Materials	Pebax 3533-7233	Unknown
Tip curve	90° in plane, 30° perpendicular	45°, 55°, 90° in plane
Accessories provided	Dilator, quick-release syringe, standard VacLok syringe, Y-connector	Dilator, J-tipped guidewire

Summary of substantial equivalence

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} 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, verification and validation testing were identified to support the substantial equivalence of the Talon Transseptal Sheath to the predicate device. These tests included:

Performance Tests

- Packaging Integrity
- Visual and Dimensional Inspections
- Guidewire and Sheath Compatibility
- Dilator Compatibility
- Test Small-Bore Connectors for Intravascular Applications
- Insertion and Removal Force of Dilator
- Simulated Use, Track and Transseptal Access
- Simulated Use, Track and Triever20 Curve Compatibility
- Shape Recovery Angles
- Simulated Use, Track and Pigtail Compatibility
- Torque Testing
- Simulated Use, Track and Kink Radius
- Simulated Use, Track and Torque Testing – Talon
- Simulated Use, Track and Torque Testing – Talon and Triever20 Curve
- Leak Testing – Sheath and Dilator
- Vacuum Testing
- Air Leakage During Aspiration
- Tensile Testing
- Particulate Evaluation
- Snare Compatibility
- Shaft Stiffness Testing
- Tip Stiffness Testing
- Force Transmission
- Flowrate through Sheath
- Torque to Failure
- Radiopacity

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications.

Animal testing was not required for the determination of substantial equivalence.

Clinical testing was not required for the determination of substantial equivalence.

Conclusion

The Talon Transseptal Sheath has the same intended use/indications for use and principles of operation as the predicate. Non-clinical performance data show that the different technological characteristics between the devices do not raise any new or different questions of safety or effectiveness and support the Talon Transseptal Sheath's substantial equivalence to the predicate device.