December 17, 2025

Inari Medical, Inc.
Kaitlyn Weinkauf
Principal Regulatory Affairs Specialist
6001 Oak Canyon
Suite 100
Irvine, California 92618

Re: K252508
Trade/Device Name: Intri26 Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 14, 2025
Received: November 17, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.12.17 22:49:43 -05'00'

for Lydia Glaw
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252508

Device Name
Intri26 Introducer Sheath

Indications for Use *(Describe)*
The Intri26 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.
• For the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

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-TRADITIONAL 510(K)

Date prepared	August 8, 2025
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Kaitlyn Weinkauf Principal Regulatory Affairs Specialist
Trade name	Intri26 Introducer Sheath
Common name	Catheter Introducer
Regulation name	Catheter Introducer
Classification number	21 CFR 870.1340
Product code	DYB, KRA
Regulatory class	II
Predicate device	Intri24 Introducer Sheath (K233646)
Reference Devices	Triever24 Catheter (K213402) GORE DrySeal Sheath with Hydrophilic Coating (K121234)
Device Description	The Intri26 Introducer 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 fluoroscopic visualization. The Intri26 dilator is compatible with a 0.035" guidewire and has a tapered leading edge, which aids insertion and positioning of the sheath.
Indications for Use	The Intri26 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. • For the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.
Summary of substantial equivalence	A tabular comparison of the predicate and subject devices is provided below. The difference is the subject device has a larger diameter than the predicates.

	Subject Device Intri26 Introducer Sheath	**Predicate Device** Intri24 Introducer Sheath	**Reference Device** Triever24 Catheter	**Reference Device** GORE DrySeal Sheath with Hydrophilic Coating
510(k) Number	TBD	K233646	K213402	K121234
Manufacturer	Inari Medical, Inc.	Inari Medical, Inc.	Inari Medical, Inc.	W.L. Gore & Associates, Inc.
Regulations	21 CFR 870.1340 Catheter introducer	21 CFR 870.1340 Catheter introducer	21 CFR 870.5150 Embolectomy Catheter	21 CFR 870.1340 Catheter introducer
Product Code	DYB, KRA	DYB	QEW, KRA	DYB

	Subject Device Intri26 Introducer Sheath	**Primary Predicate Device** Intri24 Introducer Sheath	**Secondary Predicate Device** Triever24 Catheter	**Reference Device** GORE DrySeal Sheath with Hydrophilic Coating
Intended Use/ Indications for Use	The Intri26 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. • For the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.	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.	The FlowTriever Retrieval/Aspiration System is indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Triever Catheters are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.	The Gore DrySeal Sheath with hydrophilic coating is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.
Device Description	The Intri26 Introducer 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 fluoroscopic visualization. The Intri26 dilator is compatible with a 0.035" guidewire and has a tapered leading edge, which aids insertion and positioning of the sheath.	The Intri24 Introducer 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 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 sheath.	The Triever24 Catheter is a single lumen catheter with a hemostasis valve integrated into the proximal hub. A radiopaque marker is positioned near the distal tip to aid with fluoroscopic visualization. The side port tube has a terminal quick connect coupling to allow connection for flushing or aspiration of thrombus. The Triever24 dilator is compatible with a 0.035" guidewire and has a tapered atraumatic tip, which aids in insertion and positioning of the catheter.	The GORE DrySeal Sheath consists of a hydrophilic coated introducer sheath with GORE DrySeal Valve attached, a dilator, and a syringe. The introducer sheath is a polyethylene tube with a tapered leading tip and marker band incorporated within the sheath material to allow identification under fluoroscopy. The sheath has an insert molded hub on the trailing end, which is attached to the GORE DrySeal Valve. The GORE DrySeal Valve is comprised of an outer silicone tube and an inner film tube. The dilator has a tapered leading end and provides dilatation of the access vessel. A mark on the trailing end of the dilator ensures correct positioning of the dilator with the sheath.
Principles of Operation	The Intri26 Introducer Sheath and dilator are placed over a 0.035" guidewire through the vessel puncture towards the target treatment site using fluoroscopic imaging. After positioning, the dilator is detached from the hemostasis valve and withdrawn from the patient. Endovascular devices can then be advanced through the sheath while depressing the	The Intri24 Introducer Sheath and dilator are placed over a 0.035" guidewire through the vessel puncture towards the target treatment site using fluoroscopic imaging. After positioning, the dilator is detached from the hemostasis valve and withdrawn from the patient. Endovascular devices can then be advanced through the sheath while depressing the	The Triever24 Catheter is placed over a 0.035" guidewire to a location proximal of the target thrombus. The radiopaque marker is positioned near the distal tip to aid with fluoroscopic visualization. The FlowTriever Catheter is advanced over the guidewire, through the Triever24 Catheter to a location with its tip positioned just beyond the thrombus. The	The DrySeal Sheath with hydrophilic coating and dilator are advanced over a 0.035" guidewire through the vessel puncture to the target treatment site using fluoroscopic imaging. Once the tip of the Sheath has reached the target treatment site, the dilator is withdrawn from the sheath.

	Subject Device Intri26 Introducer Sheath	**Primary Predicate Device** Intri24 Introducer Sheath	**Secondary Predicate Device** Triever24 Catheter	**Reference Device** GORE DrySeal Sheath with Hydrophilic Coating
	buttons on the hemostasis valve.	buttons on the hemostasis valve.	self-expanding FlowTriever Catheter wireform disks are deployed, and the FlowTriever Catheter is manually retracted inside the Triever24 Catheter to capture the targeted thrombus. The FlowTriever Catheter is removed from the Triever24 Catheter. The side port tube has a terminal quick release coupling to allow connection for flushing or aspiration of thrombus. Thrombus is aspirated by attaching the Large Bore 60 cc Syringe to the Triever Catheter's side port connector.	
Target Vessel	Peripheral Vasculature, ≥11 mm	Peripheral Vasculature, ≥ 9 mm	Peripheral Vasculature, ≥ 8 mm	Vasculature
Catheter Materials	Stainless Steel coil with Pebax outer cover and PTFE inner liner.	Stainless Steel coil with Pebax outer cover and PTFE inner liner.	Stainless Steel coil with Pebax outer cover and PTFE inner liner.	Stainless Steel coil with Pebax outer cover and PTFE inner liner.
Sheath / Catheter ID	26 Fr (8.9 mm)	24 Fr (7.9 mm)	21 Fr (6.9 mm)	26 Fr (8.7 mm)
Sheath / Catheter OD	9.9 mm	8.7 mm	7.6 mm	9.8 mm
Effective Length	33 cm	33 cm	90 cm	33 cm and 65 cm
Marker Band	Located at distal tip	Located at distal tip	Located at distal tip	Located at distal tip
Valve	User actuated hemostasis valve. Internal polyblend tube that expands once the spring-loaded buttons are compressed creating an open pathway for guidewire and device insertion and withdrawal.	User actuated hemostasis valve. Internal polyblend tube that expands once the spring-loaded buttons are compressed creating an open pathway for guidewire and device insertion and withdrawal.	User actuated hemostasis valve. Internal polyblend tube that expands once the spring-loaded buttons are compressed creating an open pathway for guidewire and device insertion and withdrawal.	Composed of an outer silicone tube and an inner film tube. Facilitates hemostasis without intraprocedural manipulation of the valve.
Coating	Hydrophilic coating	Hydrophilic coating	N/A	Hydrophilic coating
Dilator Shaft Material	Low Density Polyethylene	Low Density Polyethylene	Pebax, ProPell	Low Density Polyethylene
Dilator Tip	Tapered	Tapered	Tapered	Tapered
Sterilization	SAL 10^{-6}, EO	SAL 10^{-6}, EO	SAL 10^{-6}, EO	Unknown
Shelf-life	6 months	24 months	24 months	Unknown
Guidewire compatibility	0.035"	0.035"	0.035"	0.035"
Placement duration	< 24 hours	< 24 hours	< 24 hours	< 24 hours
Single-use	Yes	Yes	Yes	Yes

Summary of substantial equivalence

Biocompatibility

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Intracutaneous Reactivity
- Material-Mediated Pyrogenicity
- Sensitization
- Acute Systemic Toxicity
- Genotoxicity (Ames Assay and Mouse Lymphoma Mutagenesis Assay)

- 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 requirements per ISO 10993-1.

Sterilization

The subject device, including its accessories, is sterilized using EO 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 tests were identified to support the substantial equivalence of the Intri26 Introducer Sheath to the predicate device and reference devices. These tests included:

Verification Tests

- Pouch Seal Visual Inspection
- Bubble Leak
- Dye Penetration
- Pouch Seal Strength
- Packaging Device Retention
- Sheath Visual Inspection
- Sheath Dimensional Inspection
- Dilator Visual Inspection
- Dilator Dimensional Inspection
- Locking Cap Force and Unlocking Cap Torque
- Simulated Use, Access Site
- Dye Staining
- Coating Lubricity
- Guidewire Compatibility – Dilator
- Guidewire Compatibility – Sheath
- Insertion Force of Dilator through Sheath
- Sheath/Dilator Kink Radius and Dilator Retraction Force
- Simulated Use, Track, and Rotation
- Simulated Use, Track, and Triever26 Duo & Triever16 Curve
- Simulated Use, Track, and FlowTriever XL Catheter
- Low Pressure Fluid Leakage Testing, Dilator with Blood Analog
- Low Pressure Fluid Leakage Testing, Sheath
- Air Leakage Testing, Dilator Removal
- Air Leakage Testing, Syringe Pullback
- Vacuum Testing
- High Pressure Fluid Leakage, Blood Return
- High Pressure Fluid Leakage, Sheath
- Torque and Tensile Testing

- Engaged Axial Detachment Force Dilator Cap to Valve Cap to Valve Body
- Particulate Matter Testing
- Small Bore Connector Test
- Radiopacity
- Dilator Taper Angle (Characterization Only)
- Sheath Flow Rate (Characterization Only)
- Simulated Use, Track, and Torque 5F Catheter (Characterization Only)
- Sheath Burst (Characterization Only)
- Placement Resistance Testing, Sheath Hub (Characterization Only)
- 3 Point Bend Test (Characterization Only)
- Push Button Force Testing (Characterization Only)
- Infusion Force Testing with Triever26 Duo (Characterization Only)

Validation Tests

- GLP Animal Safety and Performance Evaluation (including functional testing/radiopacity verification)
- Dilator Insertion
- Insertion Forces
- Coating Lubricity
- Device Insertion Compatibility
- FlowTriever System Retrieval
- Manual Aspiration
- Use Device for Entire Procedure
- Use Device as a Conduit for Peripheral Access
- Glove Damage

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

Clinical Testing

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

Conclusion

The Intri26 Introducer Sheath has the same intended 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 compared to the predicate and support the Intri26 Introducer Sheath's substantial equivalence to the predicate devices.