May 12, 2025

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

Re: K250421
Trade/Device Name: InThrill™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA, DYB
Dated: February 13, 2025
Received: April 16, 2025

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 (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,

Digitally signed by ARIEL G. ASH-SHAKOOR -S
Date: 2025.05.12 11:32:06 -04'00'

For

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250421

Device Name
InThrill™ Thrombectomy System

Indications for Use *(Describe)*
The InThrill™ Thrombectomy System is indicated for:

• The non-surgical removal of emboli and thrombi from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts.
• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft.

The InThrill™ Sheath is indicated for use as a conduit for the insertion of endovascular devices into the peripheral vasculature while minimizing blood loss associated with such insertions.

The InThrill™ Thrombectomy System is intended for use in the peripheral vasculature.

The InThrill™ Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment.
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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.***

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*"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** | May 5, 2025 |
| **Name** | Inari Medical, Inc.<br>6001 Oak Canyon, Suite 100<br>Irvine, CA 92618<br>703.347.5004 |
| **Contact person** | Ellen Nguyen<br>Senior Regulatory Affairs Specialist |
| **Name of Device** | InThrill™ Thrombectomy System |
| **Product code(s)** | QEW; KRA; DYB |
| **Regulation** | 21 CFR 870.5150 Embolectomy catheter |
| **Regulatory class** | II |
| **Predicate device(s)** | Inari Medical, InThrill™ Thrombectomy System (K223613)<br>This device has not been subject to a design-related recall. |
| **Reference device(s)** | Inari Medical, Artix MT/Artix Thin-Walled Sheath (K241894)<br>Inari Medical, ClotTriever Thrombectomy System (K233815)<br>Intramed Laboratories, Inc., Graft Thrombectomy Instruments (K942457)<br>Rex Medical, Cleaner Rotational Thrombectomy System (K141617) |
| **Description** | The InThrill™ Thrombectomy System is a single-use, over-the-wire, catheter-based system for the minimally invasive treatment of thromboemboli in the peripheral vasculature, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts. The system comprises two main components packaged separately:<br>• InThrill Sheath (8 Fr)<br>• InThrill Thrombectomy Catheter (8 Fr)<br>The InThrill Sheath is placed in the target vessel, and, after its funnel is expanded, the InThrill Catheter is inserted through the sheath and advanced past the thrombus. The InThrill Catheter coring element is deployed, providing wall-to-wall contact to engage the clot, and is then retracted into the InThrill Sheath to capture the targeted thrombus. Additional clot may be removed by aspiration through the sheath with a syringe (not provided). After the procedure is complete, the InThrill Catheter and InThrill Sheath are removed from the patient. |
| **Indications for Use** | The InThrill™ Thrombectomy System is indicated for:<br>• The non-surgical removal of emboli and thrombi from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts.<br>• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft.<br>The InThrill™ Sheath is indicated for use as a conduit for the insertion of |

endovascular devices into the peripheral vasculature while minimizing blood loss associated with such insertions.

The InThrill™ Thrombectomy System is intended for use in the peripheral vasculature.

The InThrill™ Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment.

Summary of substantial equivalence

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

| | ***Subject Device***<br>InThrill™ Thrombectomy System | ***Primary Predicate***<br>InThrill™ Thrombectomy System |
|---|---|---|
| **K Number** | K250421 | K223613 |
| **Manufacturer** | Inari Medical, Inc. | Inari Medical, Inc. |
| **Product Code** | QEW, KRA, DYB | QEW, KRA |
| **Indications for Use** | The InThrill™ Thrombectomy System is indicated for:<br>• The non-surgical removal of emboli and thrombi from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts.<br>• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft.<br><br>The InThrill™ Sheath is indicated for use as a conduit for the insertion of endovascular devices into the peripheral vasculature while minimizing blood loss associated with such insertions.<br>The InThrill™ Thrombectomy System is intended for use in the peripheral vasculature.<br>The InThrill™ Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment. | The InThrill™ Thrombectomy System is indicated for:<br>• The non-surgical removal of emboli and thrombi from blood vessels, including arteriovenous fistulae and arteriovenous grafts for dialysis access, and synthetic grafts.<br>• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel/graft.<br><br>The InThrill™ Thrombectomy System is intended for use in the peripheral vasculature.<br>The InThrill™ Thrombectomy System is not intended for use in deep vein thrombosis (DVT) treatment. |
| **Sterility** | Same | SAL $10^{-6}$, EO |
| **Shelf-life** | 6 months | 2 years |
| **Guidewire compatibility** | Same | 0.035” |

| | | |
|---|---|---|
| **Device dimensions** | Same except for a longer sheath tip taper and changes to coring element (longer length, smaller diameter, and change to geometry) | Appropriately sized for the target vessel treatment range |
| **Device and packaging materials** | Same with decreased Pebax durometer at sheath shaft tip, increased Pebax durometer at catheter shaft tip, and change from two coaxial braided shaft to a single, thicker shaft | Biocompatible, commonly used materials for medical devices |
| **Accessories provided** | Dilator, pre-dilator, element support tool | Dilator, pre-dilator |

Summary of substantial equivalence

**Biocompatibility**

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Intracutaneous Reactivity
- Material-Mediated Pyrogenicity
- Hemocompatibility (Hemolysis, Complement Activation)
- Sensitization
- Acute Systemic Toxicity
- Thromboresistance (Platelet and Leukocyte Count, Partial Thromboplastin Time, and Anticoagulated Venous Implant Study)

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 InThrill™ Thrombectomy System to the predicate device. These tests included:

**Performance Tests**

Catheter - Verification:

- Visual & Dimensional
- Guidewire Compatibility
- Hemostasis
- Conditioning
- Post-conditioning Hemostasis – Sheath
- Tensile
- Corrosion
- Torque (Characterization)

System – Validation:

- Catheter Luer Connections
- Catheter Insertion and Retraction
- Device Indicators
- Sheath Funnel Wall Apposition
- Clot Burden Removal Efficacy
- Device Deployment
- Visual Inspections

Sheath - Verification:

- Visual & Dimensional
- Fluid Leakage (Pre- and Post-Conditioning)
- Air Leakage (Pre- and Post-Conditioning)
- Vacuum Testing (Pre- and Post-Conditioning)
- Simulated Use
- Retraction with Clot Analog
- Tensile
- Torque

System – Verification:

- Radial Force (Characterization)
- Pressure (Characterization)
- Graft Abrasion
- Graft Leak
- Conditioning (In-Graft Full System and Vein-to-Graft Anastomosis)
- Comparative Thrombectomy (Characterization)

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 InThrill™ Thrombectomy System 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 and support the InThrill™ Thrombectomy System's substantial equivalence to the predicate device.