March 13, 2025

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

Re: K250088
Trade/Device Name: FlowTriever2 Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: January 13, 2025
Received: January 14, 2025

Dear Rayee Patil:

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,

ARIEL G. ASH-SHAKOOR -S

Digitally signed by ARIEL G. ASH-SHAKOOR -S
Date: 2025.03.13 08:47:06 -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)*
K250088

Device Name
FlowTriever2 Catheter

Indications for Use *(Describe)*
The FlowTriever2 Catheter is indicated for:
• The non-surgical removal of emboli and thrombi from peripheral blood vessels.
• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.
The FlowTriever2 Catheter is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism (PE).

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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510(k) Summary

Date prepared	March 12, 2025
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Rayee Patil Regulatory Affairs Specialist
Trade name	FlowTriever2 Catheter
Common name	Embolectomy Catheter
Regulation name	Embolectomy Catheter
Classification number	21 CFR 870.5150
Product code	QEW, KRA
Regulatory class	II
Predicate device(s)	Inari Medical, FlowTriever2 Catheter (K201541)
Description	The Inari FlowTriever Retrieval/Aspiration System is a single-use, sterile medical device comprised of the following components, each packaged separately: • FlowTriever2 Catheter - Model 11-102 • Triever20® - Model 21-101 • Triever24® - Model 22-101 • Triever16® - Model 25-101 The FlowTriever2 Catheter is used to engage and retrieve emboli and thrombi. It consists of a coaxial catheter assembly with an outer Delivery Catheter and an inner catheter having a flexible shaft attached to distal self-expanding wireform element. A "Y" connector with a rotatable hemostatic valve and stopcock is attached to the proximal end of the outer Delivery Catheter. Radiopaque markers are positioned near the distal tip of the Delivery Catheter and at the proximal and distal ends of the self-expanding FlowTriever element to aid with fluoroscopic visualization. The Triever20 and Triever24 (packaged separately) provides a conduit for FlowTriever2 Catheter deployment, aspiration, and clot removal. 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. A Dilator compatible with a 0.035" guidewire is provided for the Triever20 and Triever24 to aid insertion.

Alternatively, the Triever16 can be tracked through the Triever Catheter (20 or 24 Fr) over the pre-inserted guidewire to a location proximal to the targeted thrombus. Thrombus is removed via aspiration using the Triever16, after which it can be withdrawn and flushed to remove residual thrombus, leaving the Triever Catheter in place as a conduit for subsequent thrombectomy passes. The user may elect to perform a thrombectomy pass using the FlowTriever2 Catheter or through the Triever16 using aspiration alone.

The Inari FlowTriever Retrieval/Aspiration System has not been evaluated for use in the neurovasculature.

Indications for Use

The FlowTriever2 Catheter is indicated for:

• The non-surgical removal of emboli and thrombi from peripheral blood vessels.
• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTriever2 Catheter is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism (PE).

Device modifications

The purpose of this submission is to expand the indications of the FlowTriever2 Catheter for the treatment of pulmonary embolism.

Comparison of Technological Characteristics with Predicate Device

There is no change to the intended use, principles of operation, or fundamental scientific technology between the proposed FlowTriever2 Catheter and the predicate device.

Summary of substantial equivalence

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

Device	FlowTriever2 Catheter Proposed (K250088)	FlowTriever2 Catheter Predicate (K201541)
Manufacturer	Inari Medical	Inari Medical
Product code	QEW, KRA	QEW, KRA
Indications for use	The FlowTriever2 Catheter is indicated for: • The non-surgical removal of emboli and thrombi from peripheral blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever2 Catheter is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.	The FlowTriever2 Catheter is indicated for: • The non-surgical removal of emboli and thrombi from peripheral blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever2 Catheter is intended for use in the peripheral vasculature.

Principals of Operation	The Triever Catheter (20 or 24 Fr) is placed over a 0.035” guidewire to a location proximal of the target thrombus. The FlowTriever2 Catheter is advanced over the guidewire, through the Triever Catheter to a location with its tip positioned just beyond the thrombus. The self-expanding disk is deployed by manually retracting the outer Delivery Catheter into the Triever Catheter. The FlowTriever2 Catheter is manually retracted inside the Triever Catheter to capture the targeted thrombus. The FlowTriever2 Catheter is removed from the Triever Catheter. Thrombus is aspirated by attaching the Large Bore 60 cc Syringe to the Triever Catheter’s side port connector. Alternatively, the Triever16 can be tracked through the Triever Catheter (20 or 24 Fr) over the pre-inserted guidewire to a location proximal to the targeted thrombus. Thrombus is removed via aspiration using the Triever16, after which it can be withdrawn and flushed to remove residual thrombus, leaving the Triever Catheter in place as a conduit for subsequent thrombectomy passes. The user may elect to perform a thrombectomy pass using the FlowTriever2 Catheter or through the Triever16 using aspiration alone..	The Triever Catheter (20 or 24 Fr) is placed over a 0.035” guidewire to a location proximal of the target thrombus. The FlowTriever2 Catheter is advanced over the guidewire, through the Triever Catheter to a location with its tip positioned just beyond the thrombus. The self-expanding disk is deployed by manually retracting the outer Delivery Catheter into the Triever Catheter. The FlowTriever2 Catheter is manually retracted inside the Triever Catheter to capture the targeted thrombus. The FlowTriever2 Catheter is removed from the Triever Catheter. Thrombus is aspirated by attaching the Large Bore 60 cc Syringe to the Triever Catheter’s side port connector. Alternatively, the Triever16 can be tracked through the Triever Catheter (20 or 24 Fr) over the pre-inserted guidewire to a location proximal to the targeted thrombus. Thrombus is removed via aspiration using the Triever16, after which it can be withdrawn and flushed to remove residual thrombus, leaving the Triever Catheter in place as a conduit for subsequent thrombectomy passes. The user may elect to perform a thrombectomy pass through the Triever16 using aspiration alone, or in combination with the FlowTriever2 Catheter.
Vessel Diameters	6-16 mm	6-16 mm
Guidewire compatibility	0.035”	0.035”
Wireform Disk Material	Laser cut nitinol	Laser cut nitinol
No. of wireform disks	1 Disk	1 Disk
Delivery catheter materials	Proximal - Pebax 7233 SA01 MED, 20% BaSO4 Distal - Pebax 4033 SA01 MED, 20% BaSO4 PTFE Liner	Proximal - Pebax 7233 SA01 MED, 20% BaSO4 Distal - Pebax 4033 SA01 MED, 20% BaSO4 PTFE Liner
Delivery catheter OD	3.8 mm	3.8 mm
Delivery catheter length	120 cm	120 cm
Catheter shaft materials	Pebax 6333 SA01 MED, PTFE Liner	Pebax 6333 SA01 MED, PTFE Liner
Tip Materials	Pebax 7233 SA01 MED, 45% Tungsten	Pebax 7233 SA01 MED, 70% Tungsten
Sterile	SAL 10^{-6}, EO	SAL 10^{-6}, EO
Shelf-Life	2 years	6 months

Summary of substantial equivalence

Biocompatibility

This submission proposes no significant design or material modifications to the FlowTriever2 Catheter. The FlowTriever2 Catheter met biological safety requirements per ISO 10993-1 per the passing results provided in K201541.

Sterilization

This submission proposes no change to the sterilization process of the FlowTriever2 Catheter. The FlowTriever2 Catheter 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

This submission proposes no significant design or material modifications to the FlowTriever2 Catheter. The design verification and validation test results provided in K201541 remain applicable.

Animal testing was not required for the determination of substantial equivalence. The *in vivo* study provided in K201541 remains applicable.

Clinical Testing

Inari Medical conducted the FlowTriever Pulmonary Embolectomy Clinical Study – FlowTriever2 (FLARE-FT2), a prospective, single-arm, multicenter confirmatory study, to evaluate the safety and effectiveness of the FlowTriever2 Catheter for the treatment of acute pulmonary embolism (PE). A total of 50 patients were enrolled at 7 study sites. The primary safety endpoint was the incidence of Serious Adverse Events (SAE), which was a composite of device-related mortality, major bleeding and intra-procedural device or procedure-related adverse events (clinical deterioration, pulmonary vascular injury, or cardiac injury) measured at 48 hours. The primary effectiveness endpoint for this confirmatory study was the change in mean and systolic pulmonary arterial pressure from baseline pre-procedure to post-procedure. The study met the performance goals for the primary study endpoints.

Conclusion

The expanded indication of the FlowTriever2 Catheter does not change its intended use, principles of operation, or fundamental scientific technology between the proposed FlowTriever2 Catheter and the predicate device. Based on the results of the FLARE-FT2 Clinical Study, the data supports that the FlowTriever2 Catheter is substantially equivalent to the predicate device.

Refer to the Instruction for Use for detailed clinical study information.