



February 6, 2023

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

Re: K221531  
Trade/Device Name: ClotTrier Thrombectomy System  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: QEW  
Dated: December 22, 2022  
Received: December 23, 2022

Dear Tosan Eweka:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Gregory W. O'Connell -S** Digitally signed by  
Gregory W. O'Connell -S  
Date: 2023.02.06  
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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

## Indications for Use

K221531

Device Name

ClotTriever Thrombectomy System

Indications for Use (*Describe*)

The ClotTriever Thrombectomy System is indicated for:

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

The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).

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.

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### 510(k) SUMMARY

Date prepared	February 3, 2023
Name	Inari Medical—Oak Canyon 6001 Oak Canyon, Suite 100 Irvine, CA 92618
Contact person	Tosan Eweka Principal Regulatory Affairs Specialist
Trade name	ClotTrieve <sup>®</sup> Thrombectomy System
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II
Predicate device	ClotTrieve Thrombectomy System (K212632)
Description	The ClotTrieve Thrombectomy System is a single-use, sterile medical device designed for use in the peripheral vasculature. The ClotTrieve Thrombectomy System consists of the ClotTrieve Sheath and the ClotTrieve Catheter. The ClotTrieve Sheath is made of a reinforced polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port and a proximal hemostatic valve. A dilator is included to aid insertion. Other provided accessories include the funnel loading tool and a large bore 60 cc syringe. The ClotTrieve Catheter is made of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Two ports terminating in stopcocks are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the sheath dilator and ClotTrieve Catheter distal tips are radiopaque.
Indications for Use	The ClotTrieve Thrombectomy System is indicated for: <ol style="list-style-type: none"> <li>1. The non-surgical removal of thrombi and emboli from blood vessels.</li> <li>2. Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.</li> </ol> <p>The ClotTrieve Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).</p>

<p>Device modifications</p>	<p>Inari is updating the labeling to replace “fibrous” and “adherent” with “predominantly fibrous” and “firmly adherent” from the list of materials contraindicated for removal using the ClotTrieve® Thrombectomy system.</p>
<p>Summary of substantial equivalence</p>	<p>The ClotTrieve® Thrombectomy System and predicate device have the same indications for use statements.</p> <p><b><u>Non-Clinical Testing</u></b></p> <p>Non-clinical testing was not required to support the change to the contraindications.</p> <p><b><u>Clinical Testing</u></b></p> <p>The CLOUT registry clinical data supporting this labeling change was originally submitted in the ClotTrieve® Thrombectomy System 510(k) (K193462, cleared on September 9, 2020). Peer-reviewed literature and published case reports were also submitted in support of this labeling change. The change to contraindications does not raise any new issues of safety or effectiveness.</p> <p><b><u>Conclusion</u></b></p> <p>The modification to replace “fibrous” and “adherent” with “predominantly fibrous” and “firmly adherent” from the list of materials contraindicated for removal using the ClotTrieve® Thrombectomy system aligns with the currently cleared indications for use and does not raise any new questions of safety and effectiveness. Therefore, the ClotTrieve® Thrombectomy system is substantially equivalent to the predicate device</p>