September 9, 2020

Inari Medical
Eben Gordon
Vice President, RA/QA
9 Parker, Suite 100
Irvine, California 92618

Re: K193462
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: July 29, 2020
Received: August 3, 2020

Dear Eben Gordon:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193462

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	September 9, 2020
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949.600.8433 x114
Contact person	Eben Gordon Vice President, Regulatory Affairs & Quality Assurance
Trade name	ClotTriever Thrombectomy System
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II
Predicate device	ZelanteDVT Thrombectomy Set (K151313)
Reference device	ClotTriever Thrombectomy System (K192332)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed for use in the peripheral vasculature. The ClotTriever Thrombectomy System consists of the ClotTriever Sheath and the ClotTriever Catheter. The ClotTriever Sheath comprises a reinforced polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port, and a proximal hemostatic valve. A dilator is provided to aid insertion. Other provided accessories include the funnel loading tool and a Large Bore 60 cc syringe. The ClotTriever Catheter comprises 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 ClotTriever Catheter distal tips are radiopaque.
Indications for Use	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).
Device modification	The Indications for Use has been changed to include the treatment of DVT and removal of the soft thrombi and emboli limitation.

Summary of substantial equivalence

The ClotTriever Thrombectomy System, predicate and reference devices have the same intended use: removal of thrombus and emboli from and infusion of fluids into the peripheral vasculature.

Non-Clinical Testing

Non-clinical testing was not required to support the change to the Indications for Use.

Clinical Testing

The ClotTriever Outcomes (CLOUT) Registry has generated real-world patient outcome information following treatment of acute and non-acute lower extremity proximal deep vein thrombosis (DVT) with the ClotTriever System. Procedural and acute data of 133 patients across 16 sites and 30-day follow-up data of 98 patients was assessed. 99.2% of patients were treated in a single session. Thrombus removal of ≥75% via core lab Marder scores was achieved in 75.2% of treated limbs, including those with chronic disease. There were 9 (6.8%) major adverse events through 30 days, none of which were device related, one (0.8%) access-site hematoma, and no acute renal injuries. At 30-day follow-up, compared to baseline, the number of patients with post-thrombotic syndrome (PTS) as well as moderate or severe PTS had both significantly decreased ($p<0.0001$). Additionally, quality of life scores, including Villalta, revised venous clinical severity score (rVCSS), EQ-5D, and numeric pain rating scale (NPRS), all showed statistically significant improvement at 30 days.

Conclusion

The specific use of treating DVT falls within the current cleared general use and real world clinical data supports the including the treatment of DVT and the removal of the soft thrombi and emboli limitation in the Indications for Use. The proposed changes to the Indications for Use do not raise new or different questions of safety and effectiveness, therefore, it can be concluded that the modified ClotTriever Catheter is substantially equivalent to the predicate device.