May 12, 2021

Inari Medical, Inc.
Larry Boucher
Regulatory Affairs Manager
9 Parker, Suite 100
Irvine, California 92618

Re: K210689
Trade/Device Name: ClotTriever Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: March 15, 2021
Received: March 16, 2021

Dear Larry Boucher:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210689

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	March 15, 2021
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949.600.8433 x114
Contact person	Larry Boucher Regulatory Affairs Manager
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	ClotTriever Thrombectomy System (K210190)
Reference Device	Cook Incorporated Dilator Sets (K183036)
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. The ClotTriever Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Three 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. Other provided accessories include a pre-dilator, the funnel loading tool and a Large Bore 60 cc syringe
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	A pre-dilator that can be inserted into and dilate the target vessel prior to the insertion of the ClotTriever Sheath will be provided with the ClotTriever system: • A 16 Fr pre-dilator will be included with the 13 Fr ClotTriever Sheath • A 19 Fr pre-dilator will be included with the 16 Fr ClotTriever Sheath The purpose for providing the pre-dilator is to assure its availability for the ClotTriever thrombectomy procedure.
Summary of substantial equivalence	The ClotTriever pre-dilator and the predicate device have the same intended use: To be used for dilating puncture sites or catheter tracts for percutaneous placement of devices. The addition of the pre-dilator does not change the intended use of the ClotTriever Thrombectomy System: removal of thrombus and emboli from and infusion of fluids into the peripheral vasculature. <u>Non-Clinical Testing</u> In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the pre-dilator. This testing demonstrated compliance with relevant product specifications. These tests included: • Visual and Dimensional Inspection • Guidewire Compatibility • Leak Testing • Simulated Use • Insertion/Kink Radius Testing • Tensile Testing • In Vivo Functional Testing/Radiopacity Verification The following testing was leveraged from K163549: • Pouch Seal Visual Inspection and Dye Penetration • Pouch, Peel, Seal Strength • Sterilization Validation Clinical testing was not required for the determination of substantial equivalence. Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications. **<u>Conclusion</u>** The proposed device modification to the ClotTriever Thrombectomy System does not change its intended use nor does it change the principles of operation. With consideration of the results of the testing, it can be concluded that the proposed pre-dilator is substantially equivalent to the predicate device.

Device	ClotTriever Thrombectomy System Proposed (TBD)	ClotTriever Thrombectomy System Predicate (K210190)	Cook Inc. Dilator Sets Reference (K183036)
Manufacturer	Inari Medical	Inari Medical	Cook Inc.
Product code	QEW, DRE	QEW	DRE
Intended use	Removal of thrombus and emboli from, and infusion of fluids into, the peripheral vasculature.	Removal of thrombus and emboli from, and infusion of fluids into, the peripheral vasculature.	Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems.
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).	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).	Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems.
Device Description	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. The ClotTriever Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Other provided accessories include a pre-dilator, the funnel loading tool and a Large Bore 60 cc syringe	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. The ClotTriever Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Other provided accessories include the funnel loading tool and a Large Bore 60 cc syringe	Cook Dilator Sets are used percutaneously to dilate puncture sites or catheter tracts, thereby facilitating the placement of other therapeutic or diagnostic devices into a natural body space (e.g., the peritoneal cavity, an artery or vein) for various vascular or non-vascular clinical applications. The dilator component of the Dilator Sets is available in diameters ranging from 3.0 to 26.0 French and in lengths ranging from 6 to 65 cm. The broad range of dilator sizes accommodates the variation in the size of the K183036 devices that could be inserted through the initial access site.

Device	ClotTriever Thrombectomy System Proposed (TBD)	ClotTriever Thrombectomy System Predicate (K210190)	Cook Inc. Dilator Sets Reference (K183036)
Principles of operation	The ClotTriever Catheter is advanced into the vessel and beyond the clot. The self-expanding braided nitinol wire net is deployed. The expanded net cores, separates, and entraps thrombus from the vessel as it is being drawn to the funnel opening of the ClotTriever Sheath. The net is collapsed and pulled into and through the ClotTriever Sheath with the entrapped clot. A 60 cc syringe is provided for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.	The ClotTriever Catheter is advanced into the vessel and beyond the clot. The self-expanding braided nitinol wire net is deployed. The expanded net cores, separates, and entraps thrombus from the vessel as it is being drawn to the funnel opening of the ClotTriever Sheath. The net is collapsed and pulled into and through the ClotTriever Sheath with the entrapped clot. A 60 cc syringe is provided for the aspiration of clot in the sheath and the infusion of contrast media and other fluids.	The dilator is advanced over a standard 0.035” guidewire into the access site prior to placement of a therapeutic or diagnostic device.
Guidewire compatibility	0.035”	0.035”	0.035”
How provided	Sterile, single use	Sterile, single use	Sterile, single use
Pre-dilator	13 Fr ClotTriever Sheath: 16 Fr Pre-dilator 16 Fr ClotTriever Sheath: 19 Fr Pre-dilator	Recommended accessory	3 Fr to 26 Fr
Pre-dilator material	LDPE/HDPE	Not provided	LDPE/HDPE