April 18, 2023

Inari Medical, Inc.
Kaitlyn Weinkauf
Sr. Regulatory Affairs Specialist
6001 Oak Canyon, Suite 100
Irvine, California 92618

Re: K230494
Trade/Device Name: ClotTriever BOLD® Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: February 23, 2023
Received: February 23, 2023

Dear Kaitlyn Weinkauf:

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.04.18 17:38:53 -04'00'

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)*
K230494

Device Name
ClotTriever BOLD®
Catheter

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	April 18, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949-600-8433
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Device name	ClotTriever® Thrombectomy System
Trade name	ClotTriever BOLD® Catheter
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Primary product code	QEW
Secondary product code	KRA
Regulatory class	II
Predicate device	ClotTriever BOLD® Catheter (K212632)
Description	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed to remove thrombi and emboli from the peripheral vasculature. The ClotTriever Thrombectomy System consists of the ClotTriever Catheter, ClotTriever BOLD Catheter, ClotTriever 13 Fr and 16 Fr Sheaths, and Protrieve Sheath, each packaged separately. The ClotTriever BOLD Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Three ports terminating in two stopcocks and a luer lock connection are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the ClotTriever Catheter, ClotTriever BOLD Catheter, ClotTriever Sheaths, and Protrieve Sheath have radiopaque distal tips.
Indications for Use	The proposed modifications of the ClotTriever BOLD Catheter do not change the indications for use of the ClotTriever Thrombectomy System. The ClotTriever Thrombectomy System is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels.

<table>
<tr><td></td><td colspan="3">• 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).</td></tr>
<tr><td>Device modifications</td><td colspan="3">The proposed modifications to the ClotTriever BOLD Catheter include: addition of a surface treatment process to the existing titanium oxide layer of the collection bag resulting in a smoother thin uniform oxide layer; dimensional change to the collection bag; dimensional change to the handle plunger shaft and addition of a hypotube in the handle; dimensional change to the coring element weld ring; change to the plunger inner compression spring; and a change to the short inner compression spring.

There are no proposed changes to the intended use or design of the ClotTriever Catheter, ClotTriever Sheaths (13 Fr and 16 Fr), and Protrieve Sheath as part of this submission.</td></tr>
<tr><td>Comparison of Technological Characteristics with the Predicate Device</td><td colspan="3">The proposed device and predicate device have a similar design and materials of construction. With the exception of the modifications listed above, the predicate and proposed devices are the same. The modifications do not change the basic design or the principles of operation from the predicate device. There are no new or different questions of safety or efficacy.

There is no change of intended use or fundamental scientific technology between the proposed device and predicate device.</td></tr>
<tr><td></td><td>Device</td><td>ClotTriever BOLD Catheter

(Proposed)</td><td>ClotTriever Thrombectomy System
ClotTriever BOLD Catheter Predicate (K212632)</td></tr>
<tr><td></td><td>Manufacturer</td><td>Inari Medical</td><td>Inari Medical</td></tr>
<tr><td></td><td>Product Code</td><td>QEW, KRA</td><td>QEW</td></tr>
<tr><td></td><td>Intended Use</td><td>The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).</td><td>The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).</td></tr>
<tr><td></td><td>Indications for Use</td><td>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).</td><td>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).</td></tr>
<tr><td></td><td>Device Description</td><td>The ClotTriever Thrombectomy System consists of the ClotTriever Sheaths, the Protrieve Sheath, the ClotTriever Catheter, and the ClotTriever BOLD Catheter. The ClotTriever/Protrieve Sheaths are comprised of a reinforced polymeric</td><td>The ClotTriever Thrombectomy System consists of the ClotTriever Sheaths, the ClotTriever Catheter, and the ClotTriever BOLD Catheter. The ClotTriever Sheaths are comprised of a reinforced polymeric sheath equipped with a self-expanding distal</td></tr>
</table>

		sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port, and a proximal hemostasis valve. The ClotTriever and ClotTriever BOLD Catheters are comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Other accessories provided include a pre-dilator, the funnel loading tool, and a large bore 60 cc syringe.	mesh funnel, a flush/aspiration port, and a proximal hemostasis valve. The ClotTriever and ClotTriever BOLD Catheters are comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Other accessories provided include a pre-dilator, the funnel loading tool, and a large bore 60 cc syringe.
	Principles of Operation	The ClotTriever BOLD 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/Protrieve Sheath. The net is collapsed and pulled into and through the ClotTriever/Protrieve 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 BOLD 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.
	Target Vessel	Peripheral vessels 6-16 mm	Peripheral vessels 6-16 mm
	Catheter OD/ID	OD: 12 Fr ID: 0.124”	OD: 12 Fr ID: 0.124”
	Collection Bag Length	Collapsed: 16.5 cm Expanded: 13.2 cm	Collapsed: 24 cm Expanded: 19 cm
	Collection Bag Material	Nitinol	Nitinol
	Collection Bag Surface	Titanium Oxide, native oxide layer and new surface treatment process to achieve a uniform thin titanium oxide layer	Titanium Oxide, native oxide layer
	Coring Element Material	Nitinol	Nitinol
	Coring Element Surface	Titanium Oxide, native oxide layer	Titanium Oxide, native oxide layer
	Coring Element OD	16 mm	16 mm
	Catheter Length	Deployed: 103 cm Effective: 80 cm	Deployed: 111 cm Effective: 80 cm
	Guidewire compatibility	0.035”	0.035”
	Shelf-Life	6 months	2 years
	Sterile	SAL 10^{-6}, EO	SAL 10^{-6}, EO
	How provided	Sterile, single use	Sterile, single use

Summary of substantial equivalence	The proposed device and predicate device have the same indications for use, intended use, principles of operation, and fundamental scientific technology. Non-Clinical Testing In accordance with the design failure modes and effects analysis, verification and validation tests were identified to support the substantial equivalence of the ClotTriever BOLD Catheter to the predicate device. This testing demonstrated compliance with relevant product specifications. The following tests were performed on the proposed device to establish substantial equivalence and shelf-life: • Packaging Usability • Visual and dimensional inspections • Deairing/Flushing • Radial force • Deployment force of ClotTriever BOLD from delivery catheter • Retraction force of handle • Retraction force of ClotTriever BOLD into delivery catheter • Leakage testing, ClotTriever BOLD Catheter • Corrosion resistance • Simulated use, track and tensile ClotTriever BOLD Catheter • Torque testing, ClotTriever BOLD handle • Particulate matter • Performance test • Clot removal from collection bag test • Narrow occlusion test The following testing was not impacted by the design modifications and therefore was leveraged from the predicate ClotTriever BOLD Catheter (K212632): • Pouch seal visual inspection • Dye penetration • Pouch, peel and seal strength • Bubble leak test • Visual and dimensional inspections post-simulated use – delivery catheter ID and marker band distance from distal tip • Guidewire compatibility • Conical fitting with 6% luer taper • Insertion of delivery catheter through ClotTriever Sheath • Retraction force of ClotTriever BOLD device through ClotTriever Sheath • ClotTriever BOLD Catheter kink radius • Leakage testing – ClotTriever Sheath • Air leakage – ClotTriever Sheath • Vacuum testing – ClotTriever Sheath • Simulated use, track, and rotation, ClotTriever BOLD Catheter • Simulated use, track and tensile, ClotTriever BOLD Catheter (*non-affected components*) • ClotTriever BOLD Catheter radiopacity

	The following design verification testing to demonstrate compatibility with the Protrieve Sheath was leveraged from the Protrieve Sheath (K220415): • Insertion of delivery catheter through Protrieve Sheath • Retraction force of ClotTriever BOLD device through Protrieve Sheath • Leakage testing – Protrieve Sheath • Air leakage – Protrieve Sheath • Vacuum testing – Protrieve Sheath As there were no new materials introduced with the design modifications, the following biocompatibility tests were leveraged from the predicate ClotTriever BOLD Catheter: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity (Systemic Injection Test and Rabbit Pyrogen Test) • Hemocompatibility (Hemolysis, Effect on Clotting, Complement Activation, and Thrombosis) The proposed ClotTriever BOLD Catheter and predicate device are of the same general construction and the design differences do not pose a greater challenge to the sterilization process. Therefore, the sterilization validation for the predicate device applies to the proposed ClotTriever BOLD Catheter. Clinical testing was not required to support 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 modifications to the ClotTriever BOLD Catheter do not change its intended use nor do they change the principles of operation. The verification and validation results demonstrate that the modified ClotTriever BOLD Catheter is substantially equivalent to the predicate device.