May 23, 2022

Inari Medical
Kit Cariquitan
VP, RA/QA
9 Parker, Suite 100
Irvine, California 92618

Re: K213402
Trade/Device Name: Triever24, Triever20
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: April 27, 2022
Received: April 28, 2022

Dear Kit Cariquitan:

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)*
K213402

Device Name
Triever24, Triever20

Indications for Use *(Describe)*
The FlowTriever Retrieval/Aspiration System is indicated for:

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

The FlowTriever Retrieval/Aspiration system is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

Triever Catheters are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.

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	October 15, 2021
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Name of Device	Triever24, Triever20
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	Inari FlowTriever Retrieval/Aspiration System (K211013) The Triever20 (K182233) was subject to a design-related recall (Z-2299-2020), initiated by Inari on March 23, 2020 and terminated by FDA on August 13, 2021.
Description	The FlowTriever Retrieval/Aspiration System is a single-use over-the-wire catheter-based system for the minimally invasive treatment of thromboemboli in the peripheral vasculature and for the treatment of pulmonary embolism. The system is comprised of two main components packaged separately: • Triever Catheters (available in 3 sizes: 16, 20, and 24 Fr) • FlowTriever Catheters (available in 4 sizes: 6-10 mm, 11-14 mm, 15-18 mm, and 19-25 mm) The FlowTriever Catheter is inserted through the Triever Catheter and advanced to the thrombus. Self-expanding wireform disks are deployed to engage thrombus by retracting the outer delivery catheter. The FlowTriever Catheter is retracted into the Triever Catheter to capture the targeted thrombus. Additional clot may be removed by aspiration with the provided 60 cc VacLok Vacuum syringe. After the procedure is complete, the Triever Catheter and FlowTriever Catheter are removed from the patient.
Indications for Use	The FlowTriever Retrieval/Aspiration System is indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

	Triever Catheters are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.
Device Modifications	The proposed modifications to the Triever24 and Triever20 devices include minor changes to the catheter shafts; material, design, and dimensional changes to the dilators; and material and dimensional changes to the hemostasis valves and sideports. The purpose of this submission is to introduce modifications to the Triever24 and Triever20 catheters which result in improved catheter deliverability and kink resistance, hemostasis valve durability and vacuum reliability, dilator support, and overall ease of use for the operator. There have been no changes to the FlowTriever Catheters.
Comparison of Technological Characteristics with the Predicate Device	The proposed devices and predicate device have a similar design and materials of construction. The modifications to the cleared Triever24 catheter proposed in this submission include a length increase and the addition of a lubricious additive to the distal shaft, a corresponding length decrease of the proximal shaft, a durometer change to the transition segment, and a stopcock lumen increase. The modifications to the cleared Triever20 catheter proposed in this submission include the addition of a transition segment, a corresponding length decrease and durometer change to the proximal shaft, and a sideport tube wall thickness increase. The modifications applicable to both Triever24 and Triever20 catheters devices proposed in this submission include catheter coil changes, hemostasis valve inner mechanism material changes, dilator material and design changes, and the removal of the Y-Connector Valve from the packaging, The modifications do not change the basic design, the indications for use, or the principles of operation from the predicate device. All Triever Catheters are tracked over the pre-placed 0.035" guidewires. The Triever16, 20, and 24 can each be used as a standalone device. The Triever16 can also be used coaxially through a Triever20 or Triever24. FlowTriever Catheters can be used for mechanical thrombectomy by deploying directly through the Triever16, Triever20, or Triever24. The way the modified Triever24 and Triever20 devices are used alone or in conjunction with the Triever16 or with the FlowTriever Catheters remains unchanged from the predicate. Therefore, there are no technological differences between the devices. There have been no changes to the FlowTriever Catheters.
Summary of substantial equivalence	There is no change of intended use or fundamental scientific technology between the proposed devices and predicate device. The Triever24 and Triever20 have the same indication for use as the predicate device, K211013. <u>Biocompatibility</u>

	The following biocompatibility tests were conducted for the subject devices: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material-Mediated Pyrogenicity • Hemocompatibility (Hemolysis, Complement Activation, Thromboresistance, Platelet and Leukocyte Count, and Partial Thromboplastin Time) The passing results demonstrate that the subject devices and accessories meet biological safety requirements per ISO 10993-1. <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 modified Triever24 and Triever20 devices. This testing demonstrated compliance with relevant product specifications. These tests, performed for both devices unless otherwise noted, include: • Visual & Dimensional Inspection – Catheter • Visual & Dimensional Inspection – Dilator • Guidewire and Dilator Compatibility Verification • 3-Point Bend Test • Removal and Insertion Force of Dilator • Retraction Force of Self-Expanding Elements into Catheter • Clot Burden Removal Validation • Air Leakage during Aspiration • Leak Test • Vacuum Test • Kink Radius Test • Flow Rate through Catheter (Triever24 only) • Stopcock Misuse Leakage Test (Triever24 only) • Simulated Use and Tensile Test – Catheter and Dilator • Simulated Use and Tensile Test – Stopcock (Triever24 only) • Simulated Use and Tensile Test – Swivel Hub and Sideport (Triever20 only) • Torque Test – Stopcock (Triever24 only) and Catheter • Locking/Unlocking Force and Torque between Dilator and Catheter Hub • Particulate Matter The following testing was leveraged from previously cleared Inari devices for both devices unless otherwise noted: • Pouch Seal Visual Inspection and Dye Penetration • Pouch, Peel, Seal Strength

	• Guidewire and Catheter Compatibility (Partial, Triever24 only) • Test Small-Bore Connectors for Intravascular Applications • Catheter Burst • Corrosion Resistance • Particulate Matter (Partial) • Sheath Compatibility • Push-Button Force Testing – Garrote Valve Animal testing was not required for the determination of substantial equivalence. Clinical testing was not required for the determination of substantial equivalence. Test results demonstrated that all acceptance criteria were met; therefore, the devices conform to established product specifications. **Conclusion** The proposed device modifications to the Triever24 and Triever20 devices do not change its intended use nor the principles of operation. With consideration of the results of testing, it can be concluded that the modified Triever24 and Triever20 devices are substantially equivalent to the predicate device.