March 23, 2023

Inari Medical
Ellen Nguyen
Regulatory Affairs Specialist
6001 Oak Canyon, Suite 100
Irvine, California 92618

Re: K223419
Trade/Device Name: Triever16 Curve
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: February 23, 2023
Received: February 24, 2023

Dear Ellen Nguyen:

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: 2023.03.23 09:30:19 -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)*
K223419

Device Name
Triever16 Curve

Indications for Use *(Describe)*
The Triever16 Curve 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 Triever16 Curve is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

The Triever16 Curve is not indicated for use with FlowTriever Catheters.

The Triever16 Curve is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Date prepared	March 22, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Ellen Nguyen Regulatory Affairs Specialist
Name of Device	Triever16 Curve
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Secondary product code	KRA
Regulatory class	II
Predicate device	Inari FlowTriever Retrieval/Aspiration System (K213402)
References devices	Penumbra Indigo System Aspiration Catheter 12 (K192981)
Description	The Triever16 ("T16") Curve is a single-use, over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature, the treatment of pulmonary embolism, and the treatment of clot in transit in the right atrium. The T16 Curve is inserted over a pre-placed 0.035" guidewire, either standalone (i.e., through an introducer sheath without another catheter) or through a compatible Inari device such as the Triever20/24, Intri24 Sheath, 16 Fr ClotTriever Sheath, or Protrieve Sheath (packaged separately), and advanced to the thrombus. Thrombus is removed by aspiration with the provided 60 cc Large Bore Vacuum syringe. After the procedure is complete, the T16 Curve is removed from the patient.
Indications for Use	The Triever16 Curve 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 Triever16 Curve is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever16 Curve is not indicated for use with FlowTriever Catheters. The Triever16 Curve is 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 Triever20 ("T20") Curve include dimensional and material changes to both the catheter and dilator.

These modifications introduce the Triever16 Curve, a T20 Curve variant used for aspiration thrombectomy in the peripheral vasculature, pulmonary arteries, and right heart.

Comparison of Technological Characteristics with the Predicate Device

The proposed modifications do not change the intended use or principles of operation from the predicate device. The modified and predicate device have a similar design and mainly differ in dimensions and materials.

The Triever16 Curve and Triever20 Curve are both tracked over a pre-placed compatible guidewire. The Triever16 Curve performs thrombectomy using aspiration, following the same method as the predicate Triever20 Curve.

Although the predicate and subject devices have different technological characteristics, all leveraged and performed design verification and validation tests confirm that these differences do not raise any new or different questions of safety or effectiveness.

There have been no changes to the 16/20/24 Fr Triever Catheters or FlowTriever Catheters.

Summary of substantial equivalence

There is no change of intended use or fundamental scientific technology between the proposed device and predicate device. Aside from the Triever20 Curve's requirement to be used through the Triever24, the Triever16 Curve has the same indications for use as the predicate device, K213402: both are indicated for the non-surgical removal of emboli and thrombi from blood vessels and the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. Both are intended for use in the peripheral vasculature, for the treatment of pulmonary embolism, and for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.

A tabular comparison of specific technological characteristics between the predicate and subject device is provided below:

Feature	Triever16 Curve Proposed (TBD)	Triever20 Curve Predicate (K213402)
Manufacturer	Inari Medical	Inari Medical
Product code	QEW	QEW
Intended use/Indications for use	The Triever16 Curve 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 Triever16 Curve is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.	The Triever20 Curve is used coaxially within the Triever24 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 Triever20 Curve is intended for use in the peripheral vasculature and for the treatment of pulmonary

Feature	Triever16 Curve Proposed (TBD)	Triever20 Curve Predicate (K213402)
	The Triever16 Curve is not indicated for use with FlowTriever Catheters. The Triever16 Curve is also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.	embolism. The Triever20 Curve is not indicated for use with FlowTriever Catheters. The Triever20 Curve is also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.
Principles of operation	The Triever16 Curve is inserted into the vessel standalone or through a compatible Inari device over a pre-placed guidewire and is advanced until its tip is proximal to the target thrombus. A 60 cc syringe is provided for the aspiration of clot into the catheter and the infusion of contrast media and other fluids.	The Triever20 Curve is inserted into the vessel through the Triever24 over a pre-placed guidewire and is advanced until its tip is proximal to the target thrombus. A 60 cc syringe is provided for the aspiration of clot into the catheter and the infusion of contrast media and other fluids.
Target vessel	Peripheral vessels $\geq$ 6 mm, pulmonary arteries, right heart, IVC	Peripheral vessels $\geq$ 8 mm, pulmonary arteries, right heart, IVC
Contraindicated vessels	< 6 mm	< 8 mm
Guidewire compatibility	0.035”	0.035”
Shelf-life	2 years	2 years
Sterilization	EtO	EtO
Single-use	Yes	Yes
Catheter		
Dimensions	OD/ID: 16 Fr (5.3 mm)/4.5 mm Length: 110 cm	OD/ID: 20 Fr (6.8 mm)/5.6 mm Length: 102 cm
Shaft material	Distal: Pebax 55D with ProPell Transition: Pebax 35D and 55D with ProPell Proximal: Pebax 63D	Distal: Pebax 35D Transition: Pebax 55D Proximal: Pebax 72D
Metal support	Braid: 110.7 cm Coil: 45.7 cm	Braid: 101.6 cm Coil: 40.64 cm
Hemostasis valve	Septum: Polyblend/adhesive Monofilament: Braided polyester	Septum: Braid/silicone Monofilament: Nylon
Tip angle	110°	225°

Feature	Triever16 Curve Proposed (TBD)	Triever20 Curve Predicate (K213402)
Dilator		
Length	118.9 cm	113.3 cm
Materials	Pebax 55D with ProPell	LDPE/HDPE
Handle	Overmolded locking hub	Luer connection

Biocompatibility

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Intracutaneous Reactivity
- Material-Mediated Pyrogenicity
- Hemocompatibility (Hemolysis, Complement Activation, Thromboresistance, Platelet and Leukocyte Count, and Partial Thromboplastin Time)
- Sensitization
- Acute Systemic Toxicity

The passing results demonstrate that the subject device and accessories meet biological safety requirements per ISO 10993-1.

Sterilization

The subject device, including its accessories, is sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6}. The subject device has been adopted into a validated sterilization process in accordance with the principles of ISO 11135:2014/Amd 1:2018 (*Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E, Single batch release*) and AAMI TIR 28:2016 (*Product adoption and process equivalence for ethylene oxide sterilization*) without deviations.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the substantial equivalence of the Triever16 Curve. These tests included:

- Visual & Dimensional Inspection - Catheter
- Visual & Dimensional Inspection - Dilator
- Guidewire Compatibility
- Insertion and Retraction Force through 16 Fr Introducer Sheath
- Rotation inside 16 Fr Introducer Sheath
- Recovery Angle
- Kink Radius
- Vacuum Testing
- Catheter and Dilator Flow Rate Testing
- Clot Burden Removal Validation
- Simulated Use, Track & Tensile

- Simulated Use, Track & Torque

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications.

Neither animal testing nor clinical testing were required for the determination of substantial equivalence.

Conclusion

The Triever16 Curve has the same intended use/indications for use and principles of operation as the predicate. Performance data shows that the different technological characteristics between the devices do not raise any new or different questions of safety or effectiveness. Non-clinical bench testing supports the Triever16 Curve's substantial equivalence to the predicate device.