July 21, 2023

Inari Medical Inc.
Anthony Lam
Sr. Manager Regulatory Affairs
6001 Oak Canyon
Suite 100
Irvine, CA 92618

Re: K231848
Trade/Device Name: Triever20 Curve (21-201)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: June 25, 2023
Received: June 26, 2023

Dear Anthony Lam:

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.07.21 14:56:23 -04'00'

For

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)*
K231848

Device Name
Triever20 Curve (21-201)

Indications for Use *(Describe)*
The Triever20 Curve (21-201) 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 (21-201) is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

The Triever20 Curve (21-201) Catheter is not indicated for use with FlowTriever Catheters.

Triever20 Curve (21-201) is also intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTriever Catheters.

The Triever20 Curve (21-201) must be used within the Triever24.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date prepared	July 21, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Anthony Lam Sr. Manager Regulatory Affairs
Name of Device	Triever20 Curve (21-201)
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 Medical, Inari FlowTriever Retrieval/ Aspiration System (K213402) This device has not been subject to a design-related recall.
Reference device	Inari Medical, Triever20 Curve (K203333)
Description	Triever20 Curve, Model 21-201 is a single-use over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature and the treatment of pulmonary embolism. A Dilator is provided with the Triever20 Curve Catheter to assist in its advancement over a preplaced 0.035" guidewire to the proximal end of the obstruction (thrombus). The Triever24 Catheter is inserted through an introducer sheath (not provided). After Triever24 Catheter placement, the Dilator is removed. The Triever20 Curve Catheter is then inserted through the Triever24 Catheter and advanced to the thrombus. Thrombus is removed by aspiration with the provided 60 cc Large Bore Syringe.
Indications for Use	The Triever20 Curve (21-201) 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 (21-201) is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever20 Curve (21-201) Catheter is not indicated for use with FlowTriever Catheters.

<table>
<tr><td></td><td>Triever20 Curve (21-201) is also intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTriever Catheters.
The Triever20 Curve (21-201) must be used within the Triever24.</td></tr>
<tr><td>Device Modifications</td><td>The device modifications associated with implementing the Triever20 Curve are:
A. Removed the Y-connector from the packaging
B. Increase in overall catheter length from 43.38” to 43.76”
C. Shaft jacket length change
D. Hemostasis valve septum and monofilament material change
E. Upgraded dilator
F. Garrote valve updated to include locking cap for the dilator
G. Tapered distal tip change
H. Replaced braid and coil with multifilar coil
I. Backer card changes</td></tr>
<tr><td>Comparison of Technological Characteristics with the Predicate Device</td><td>The proposed modifications do not change the intended use or principles of operation from the predicate device. The modified and reference device have a similar design and mainly differ in dimensions and materials.
The modified Triever20 Curve and Triever20 Curve are both tracked over a pre-placed compatible guidewire. The Triever20 Curve Generation 2 performs thrombectomy using aspiration, following the same method as the reference 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.</td></tr>
<tr><td>Summary of substantial equivalence</td><td>There is no change of intended use or fundamental scientific technology between the proposed device, reference, and predicate device. Aside from device modifications, the Triever20 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 reference and subject device is provided below:
<table>
<tr><th>Feature</th><th>Triever20 Curve (21-201) Proposed (K231848)</th><th>Triever20 Curve Reference (K203333)</th></tr>
<tr><td>Manufacturer</td><td>Inari Medical</td><td>Inari Medical</td></tr>
<tr><td>Product code</td><td>QEW</td><td>QEW</td></tr>
<tr><td>Intended use/Indications for use</td><td>The Triever20 Curve (21-201) 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</td><td>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</td></tr>
</table></td></tr>
</table>

		and other fluids into or from a blood vessel. The Triever20 Curve (21-201) is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever20 Curve (21-201) Catheter is not indicated for use with FlowTriever Catheters. Triever20 Curve (21-201) is also intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTriever Catheters. The Triever20 Curve (21-201) must be used within the Triever24.	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 embolism. The Triever20 Curve Catheter is not indicated for use with FlowTriever Catheters.
	Principles of operation	The Triever20 Curve (21-201) is inserted over a pre-placed guidewire and through a Triever24 Catheter to a location proximal of the targeted thrombus. The proximal hemostasis valve can be rotated to assist targeting the angled tip. After removing the dilator, thrombus aspiration can be performed using the 60 cc Large Bore Syringe. FlowTriever Catheters can be used for mechanical thrombectomy by removing the Triever20 Curve and either: 1) deploying directly through the Triever24; or 2) replacing the Triever24 with a Triever20 and then deploying the FlowTriever Catheter.	The Triever20 Curve is inserted over a pre-placed guidewire and through a Triever24 Catheter to a location proximal of the targeted thrombus. The proximal hemostasis valve can be rotated to assist targeting the angled tip. After removing the dilator, thrombus aspiration can be performed using the 60 cc Large Bore Syringe. FlowTriever Catheters can be used for mechanical thrombectomy by removing the Triever20 Curve and either: 1) deploying directly through the Triever24; or 2) replacing the Triever24 with a Triever20 and then deploying the FlowTriever Catheter.
	Target vessel	Peripheral vessels $\geq$ 8 mm, pulmonary arteries, right heart, IVC	Peripheral vessels $\geq$ 8 mm, pulmonary arteries, right heart, IVC
	Contraindicated vessels	< 8 mm	< 8 mm
	Guidewire compatibility	0.035”	0.035”
	Shelf-life	6 months	2 years
	Sterilization	EtO	EtO
	Single-use	Yes	Yes
	Catheter		
	Dimensions	OD/ID: 20 Fr (6.8 mm)/5.6 mm	OD/ID: 20 Fr (6.8 mm)/5.6 mm

	Length: 111 cm	Length: 110 cm
Shaft material	Proximal: Pebax 72D Middle: Pebax 55D Distal: Pebax 35D Tip: 72D	Proximal: Pebax 72D Middle: Pebax 55D Distal: Pebax 35D Tip: 72D
Shaft support	304V Stainless Steel Multifilar Coil	304V Stainless Steel braid and coil
Hemostasis valve	Septum: Polyblend/adhesive Monofilament: Braided polyester	Septum: Braid/silicone Monofilament: Nylon
Tip angle	225°	225°
Dilator		
Length	112 cm	111.65 cm
Materials	Pebax 55D with ProPell Pebax 35D with ProPell	LDPE/HDPE
Handle	Overmolded locking hub	Luer connection

A tabular comparison of the intended use between the predicate and subject device is provided below:

Feature	**Triever20 Curve (21-201) Proposed (K231848)**	**FlowTriever Retrieval/Aspiration System Predicate (K213402)**
Manufacturer	Inari Medical	Inari Medical
Product code	QEW	QEW
Secondary Product code	KRA	KRA
Intended use/Indications for use	The Triever20 Curve (21-201) 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 (21-201) is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever20 Curve (21-201) Catheter is not indicated for use with FlowTriever Catheters.	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

	Triever20 Curve (21-201) is also intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTriever Catheters. The Triever20 Curve (21-201) must be used within the Triever24.	not in conjunction with FlowTriever Catheters.

Biocompatibility

The following biocompatibility tests were completed for the subject device:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

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} using a validated sterilization process in accordance with the principles of ISO 11135:2014/Amd 1:2018 and AAMI TIR 28:2016.

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 modified Triever20 Curve. These tests included:

• Pouch Seal Visual Inspection
• Bubble Leak Test
• Dye Penetration
• Packaging Integrity, Visual Inspection
• Visual and Dimensional
• Dilator Compatibility
• T20 Curve Dilator Insertion and Removal
• T20 Curve Insertion and Retraction from T24/Protrieve
• T20 Curve Rotation within T24/Protrieve
• T20 Curve Recovery Angle
• Kink Radius
• Torque Testing
• Simulated Use Track & Tensile (catheter tested)
• Simulated Use Track & Torque – (catheter tested)
• Clot Burden Removal Validation
• Vacuum Testing – Resistance to collapse under vacuum
• Determination of Flowrate Through Catheter & Dilator

	• Particulate Matter Determination The following testing was not impacted by the design modifications and therefore was leveraged from the reference device, Triever20 Curve (K203333): • Pouch, Peel, Seal Strength • Aseptic Presentation • Label Integrity, Visual Inspection • Guidewire Compatibility • Unlocking/Locking force/torque and Connection of Dilator Cap to Guide Catheter Hemostasis Valve Cap • Push-button force testing – Garrote valve • Leakage Testing • Air leakage during aspiration • Capable of being de-aired • Simulated Use Track & Tensile (dilator and sideport leveraged) • Vacuum Testing – Sufficient vacuum generated for thrombus aspiration • Vacuum Testing – Flushing Stopcock • Functional Testing – Large Bore Syringe • Luer Lock Connection • Dilator Burst • Catheter Burst • Radiopacity Testing • Corrosion Resistance Neither animal testing nor clinical testing were required for the determination of substantial equivalence. Test results demonstrated that all acceptance criteria were met; the device conforms to established product specifications. **Conclusion** The modified Triever20 Curve has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports the modified Triever20 Curve substantial equivalence to the predicate device.