December 10, 2020

Inari Medical, Inc.
Ellen Nguyen
Regulatory Affairs Associate
9 Parker, Suite 100
Irvine, California 92618

Re: K203333
Trade/Device Name: Triever20 Curve Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: November 11, 2020
Received: November 12, 2020

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 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)*

Device Name
Triever20 Curve Catheter

Indications for Use *(Describe)*
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 embolism.

The Triever20 Curve Catheter is not indicated for use 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	November 11, 2020
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Ellen Nguyen Regulatory Affairs Associate
Trade name	Triever20 Curve Catheter
Common name	Embolectomy catheter
Regulation name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	QEW
Regulatory class	II
Predicate device	Inari FlowTriever Retrieval/Aspiration System (K191710)
Description	The Triever20 Curve is a single-use over-the-wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature and for the treatment of pulmonary embolism. The Triever20 Curve Catheter is inserted through the Triever24 Catheter 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 Triever Catheters are removed from the patient.
Indications for Use	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 embolism. The Triever20 Curve Catheter is not indicated for use with FlowTriever Catheters.

Device modifications	The device modifications associated with implementing the Triever20 Curve with an angled tip: • Proximal shaft durometer change from 63D Pebax to 72D Pebax • Length of 35D Pebax distal shaft increased 7.6 cm (29.2 to 36.8 cm) • 6.4 cm of 55D Pebax added between proximal and distal shaft segments • 0.6 cm of 72D Pebax added to distal shaft tip • Catheter length increase of 14.8 cm (90.2 cm to 105.0 cm) • Catheter OD increase of 0.009" (0.257" to 0.266") • Bonding the proximal Hemostasis Valve to render it non-rotatable • Dilator length increase of 15 cm (96 to 111 cm)
Summary of substantial equivalence	There is no change of intended use or fundamental scientific technology between the proposed and predicate device. The Triever20 Curve has the same indication for use as the predicate, K191710. <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 Triever20 Curve. This testing demonstrated compliance with relevant product specifications. These tests included: • Package Integrity Inspection • Visual & Dimensional Inspection • Guidewire and Dilator Compatibility Verification • Triever20 Curve Dilator Insertion and Removal • Triever20 Curve Insertion into Triever24 and Retraction • Triever20 Curve Rotation inside Triever24 • Triever20 Curve recovery angle • Kink Radius • Torque Test 1 • Torque Test 2 • Resistance to collapse under vacuum • Determination of Flowrate Through Catheters & Dilator • Burst Testing – Triever20 Curve Catheter • Clot Burden Removal Validation • Simulated Use and Tensile Testing – Torque • Simulated Use and Tensile Testing - Tensile • Simulated Use and Tensile Testing – Triever20 Curve Dilator • Particulate Matter Determination The following testing was leveraged from K173672: • Pouch Seal Visual Inspection and Dye Penetration • Pouch, Peel, Seal Strength

	• Test Conical Fittings with 6% Luer taper • Corrosion Resistance • No air bubbles from fluid drawback • Hemostasis • Priming of the system • Snap fit • Sufficient vacuum • Pyrogenicity • Device Insertion • Luer Lock Connection • Dilator: Hub to Shaft attachment; Proximal shaft to Distal shaft attachment; Tip to Shaft attachment • Hub and Catheter Leakage • Dilator Burst 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 device conforms to established product specifications. <u>Conclusion</u> The proposed device modifications to the Triever20 Curve do 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 Triever20 Curve is substantially equivalent to the predicate device.