February 17, 2023

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

Re: K221483
Trade/Device Name: FlowSaver Blood Return System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: December 16, 2022
Received: December 20, 2022

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*

K221483

Device Name
FlowSaver Blood Return System

Indications for Use *(Describe)*
The FlowSaver Blood Return System is used with Triever Catheters for autologous blood transfusion.

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	February 16, 2023
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 949.600.8433
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Trade name	FlowSaver Blood Return System
Common name	Blood filter
Regulation name	Autotransfusion apparatus
Classification number	21 CFR 868.5830
Product code	CAC
Regulatory class	II
Predicate device	FlowSaver Blood Return System (K210176)
Description	The FlowSaver Blood Return System accessory allows for autologous injection of aspirated blood from the FlowTriever Retrieval/Aspiration System embolectomy procedure by dual layer 40 μ/200 μ filtration to minimize intraprocedural blood loss.
Indications for Use	The FlowSaver Blood Return System is used with Triever Catheters for autologous blood transfusion.
Device modification	The purpose of this submission is a labeling change to remove the secondary filtration procedure that is performed after the initial filtration with the FlowSaver Blood Return System.
Comparison of Technological Characteristics with the Predicate Device	There is no change to the principles of operation, indications for use, intended use, fundamental scientific technology, or technological characteristics between the proposed FlowSaver Blood Return System and the predicate device.

Summary of substantial equivalence	The proposed FlowSaver Blood Return System accessory and the predicate device have the same indications for use, intended use, principles of operation, and fundamental scientific technology. **Non-Clinical Testing** The following verification test demonstrated compliance with product requirements: • Filtration Efficiency The following testing was leveraged from the predicate device (K210176): • Visual Inspection • Dimensional Inspection • Engagement & Disengagement Force Testing • Flow Rate Testing • Media Integrity testing • Leakage Testing • Vacuum Testing • Clot Burden Filtration Validation • Simulated Use and Tensile Testing • Simulated Use and Torque Testing • Burst Testing • Hematocrit Testing • Mechanical Hemolysis Testing Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications. **Clinical Testing** Post-market clinical data was used to demonstrate the safety and effectiveness of the FlowSaver Blood Return System's use without a secondary filtration procedure. Post-market clinical data from PEERLESS (NCT05111613), FLAME (NCT04795167), and FLASH (NCT03761173) studies demonstrated the FlowSaver's filtration efficiency and safety without use of the second filter in support of substantial equivalence. **Conclusion** The proposed labeling change to the FlowSaver Blood Return System does not change its intended use nor does it change the principles of operation. The verification testing results demonstrate that the proposed FlowSaver Blood Return System is substantially equivalent to the predicate device.