July 14, 2023

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

Re: K231782
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: June 16, 2023
Received: June 16, 2023

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,

Kathleen M. Grunder -S

for 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)*
K231782

Device Name
FlowSaver Blood Return System

Indications for Use *(Describe)*
The FlowSaver Blood Return System is used with Inari Medical catheters and sheaths 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.

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

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510(K) SUMMARY

Date prepared	July 14, 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	Inari Medical, FlowSaver Blood Return System (K221483)
Description	The FlowSaver Blood Return System accessory allows for autologous injection of aspirated blood from Inari Medical catheters and sheaths during embolectomy procedures by dual layer 40 μm/200 μm filtration to minimize intraprocedural blood loss.
Indications for Use	The FlowSaver Blood Return System is used with Inari Medical catheters and sheaths for autologous blood transfusion.
Device Modifications	The purpose of this submission is to expand the indications of the FlowSaver Blood Return System to be used with Inari Medical catheters and sheaths for autologous blood transfusion, and for use with the 30 cc large bore syringe.
Comparison of Technological Characteristics with the Predicate Device	There is no change to the intended use, technological characteristics, principles of operation, or fundamental scientific technology between the proposed FlowSaver Blood Return System and the predicate device.
Summary of substantial equivalence	The proposed FlowSaver Blood Return System and the predicate device have the same intended use, principles of operation, fundamental scientific technology, and technological characteristics. **Non-Clinical Testing** Design verification testing was not required to support substantial equivalence for the expanded indications and the testing performed in K210176 and K221483 remains applicable to support the use of the FlowSaver with Inari Medical catheters and sheaths for autologous blood transfusion. Mechanical hemolysis testing was performed to demonstrate substantial equivalence to the predicate.

	The following testing was leveraged from 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 • Particulate Matter Determination The following testing was leveraged from K221483: • Filtration Efficiency **Clinical Testing** Clinical testing was not required to support substantial equivalence. **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. **Conclusion** The proposed FlowSaver Blood Return System indication expansion 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.