July 22, 2021

Inari Medical
Eben Gordon
Vice President, Regulatory Affairs and Quality Assurance
9 Parker, Suite 100
Irvine, California 92618

Re: K210176
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: July 9, 2021
Received: July 12, 2021

Dear Eben Gordon:

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 Gillette
Assistant Director (Acting)
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)*
K210176

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	July 16, 2021
Name	Inari Medical, Inc. 9 Parker, Suite 100 Irvine, CA 92618 949.418.4095
Contact person(s)	Eben Gordon Vice President, Regulatory Affairs & Quality Assurance
Name of device	FlowSaver Blood Return System
Common name	Blood filter accessory
Regulation name	Autotransfusion apparatus
Classification number	21 CFR 868.5830
Product code	CAC
Regulatory class	II
Predicate device	CellTrans Postoperative Autotransfusion Set, K024097 This predicate has not been subject to a design-related recall.
Reference device(s)	FlowTriever Retrieval/Aspiration System (K191710) This reference device has not been subject to a design-related recall. Charter Medical Neonatal Syringe Set (K000685) This reference device has not been subject to a design-related recall.
Device description	The FlowSaver Blood Return System accessory allows for autologous injection of aspirated blood from the FlowTriever Retrieval/Aspiration System embolectomy procedure. The sterile (EO), single use FlowSaver Blood Return System is comprised of 2 components: • FlowSaver Blood Filter • 60 cc Luer Lock Syringe The FlowSaver Blood Filter has a sideport with a female quick connector for connection to the 60 cc Large Bore Vacuum Syringe (provided with Triever Catheter). Another standard Luer lock 60 cc syringe (provided) is attached to the needleless valve integrated into the FlowSaver's cap. The aspirant from a Triever Catheter embolectomy procedure is injected into the FlowSaver Blood Filter. Blood passes through the FlowSaver's dual layer 40 µ/200 µ polyester screen filter, filling the 60 cc syringe pre-connected to the female Luer Lock that is integrated into the cap of the filter housing. The 60 cc syringe is disconnected and its contents are injected through a suitable transfusion filter (minimum requirement 40 micron filter) prior to immediately reinjecting collected blood through an access sheath or catheter to reintroduce into the patient. FlowSaver's threaded cap with filter may be

detached allowing rinsing with saline to remove thrombus and permit re-use if another Triever aspiration is performed. The FlowSaver may be used for up to five filtrations.

Indications for Use

The FlowSaver Blood Return System is used with Triever Catheters for autologous blood transfusion.

Comparison of technological characteristics with the predicate device

The FlowSaver is similar to the predicate device with respect to the intended use and technological characteristics. Both devices are intended to be used to return blood to a patient after filtration through a 40-micron filter. The collection method for the proposed and predicate device is through vacuum aspiration. Contaminants for both devices are removed the same via filtration through polyester screens. The lack of the cell processing of contaminants capability of the Celltrans' Pall LipiGuard filter is not meaningful for the FlowSaver since it is not used to filter salvaged blood. While the FlowSaver filters blood through dual layer 40 μ/200 μ polyester screens, CellTrans blood is filtered through polyester 200 μ and 40 μ screens and a depth filter for salvaged contaminants. The lack of depth filtration exposes blood cells to less trauma. Since the principle of operation, blood filtration is the same, there are no new questions of safety or effectiveness. Inari Medical performed comprehensive testing on the FlowSaver, including non-clinical bench testing to demonstrate that the device met all required specifications and performs as intended. The testing demonstrated that the technological differences do not raise any different questions of safety and effectiveness from the predicate device.

Summary of substantial equivalence

The FlowSaver Blood Return System and the predicate device have the same intended use to filter blood for autologous blood transfusion and are substantially equivalent with regard to performance and technological characteristics. The FlowSaver Blood Return System and the reference device have similar technological characteristics. The minor differences between the subject device, the predicate device, and the reference device have been evaluated and determined to not raise any different questions of safety and effectiveness.

Non-Clinical Testing

The following verification and validation tests demonstrated compliance with product requirements:

- Visual Inspection
- Dimensional Inspection
- Engagement & Disengagement Force Testing
- Flow Rate Testing
- Media Integrity testing
- Leakage Testing
- Vacuum Testing
- Clot Burden Filtration Validation
- Preconditioning/Simulated Use and Tensile Testing
- Preconditioning/Simulated Use and Torque Testing
- Burst Testing
- Hematocrit Testing
- Mechanical Hemolysis Testing

- Filtration Efficiency
- Particulate Matter Determination

Biocompatibility testing was conducted in accordance FDA Guidance Document for the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued 09/4/2020) guidelines. The FlowSaver filter passed the following tests:

- ISO Medium Eluate Method (MEM) Elution Test
- ISO Kligman Maximization Test in Guinea Pigs Sensitization Test
- ISO Intracutaneous Injection Test in Rabbits
- ISO Systemic Injection Test in Mice
- ISO Rabbit Pyrogen (Material- Mediated) Test
- ASTM Hemolysis Test - Rabbit Blood – Direct and Indirect Contact Methods
- ISO Unactivated Partial Thrombinplastin Time (UPTT) Test – Direct Contact Method
- ISO Complement Activation (C3 and SC5b-9) Test – Direct Contact
- Platelet and Leukocyte Count Test (Direct Contact) – ASTM
- Partial Thromboplastin Time Test (Direct Contact) - ASTM

Clinical testing was not required for the determination of substantial equivalence.

Conclusion

Extensive performance testing has been performed on FlowSaver to evaluate the overall performance of the device. The collective results from the non-clinical testing confirms that the device meets its specifications and exhibits the required medical and functional characteristics for its intended use to filter and infuse autologous blood and as such, is substantially equivalent to the predicate device.