March 26, 2024

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

Re: K233069
Trade/Device Name: Removal System Large Bore 60 cc Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: PUR
Dated: February 22, 2024
Received: February 22, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

Submission Number *(if known)*

K233069

Device Name

Removal System Large Bore 60 cc Syringe

Indications for Use *(Describe)*

The Removal System Large Bore 60 cc Syringe is used with the Removal Catheters to inject fluids into or withdraw fluids and/or tissues from the body. It can be used for aspiration removal of fluid and/or tissue in the form of abscess fluid, infected materials, etc.

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	March 25, 2024
Name	Inari Medical, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618 877.923.4747
Contact person	Kaitlyn Weinkauf Sr. Regulatory Affairs Specialist
Trade name	Removal System Large Bore 60 cc Syringe
Common name	Vacuum Syringe
Regulation name	Piston Syringe
Classification number	21 CFR 880.5860
Product code	PUR
Regulatory class	II
Predicate device(s)	Merit VacLok AT Vacuum Syringe (K163597)
Device description	The Removal System Large Bore 60 cc Syringe is a general piston syringe constructed using a barrel, plunger, plunger seal, and large bore Toomey tip adapter that acts as a quick-release connector. The quick-release connector is compatible with the Removal System Catheters' sideport connector to establish an airtight seal. The twist-to-lock plunger with barrel tabs maintains the retracted position of the plunger.
Indications for Use	The Removal System Large Bore 60 cc Syringe is used with the Removal Catheters to inject fluids into or withdraw fluids and/or tissues from the body. It can be used for aspiration removal of fluid and/or tissue in the form of abscess fluid, infected materials, etc.
Summary of substantial equivalence	A tabular comparison of the predicate and subject devices is provided below:

	Subject Device Removal System Large Bore 60 cc Syringe	***Primary Predicate Device*** Merit VacLok AT Vacuum Syringe	**Comments**
510(k) Number	K233069	K163597	-
Manufacturer	Inari Medical, Inc.	Merit Medical Systems, Inc.	-
Regulation	21 CFR 880.5860 Piston Syringe	21 CFR 880.5860 Piston Syringe	Identical.
Product Code	PUR	PUR	Identical.
Intended Use	To inject fluids into or withdraw fluids from the	To inject fluids into or withdraw fluids from the	Identical.

	body.	body.	
Indications for Use	The Removal System Large Bore 60 cc Syringe is used with the Removal Catheters to inject fluids into or withdraw fluids and/or tissues from the body. It can be used for aspiration removal of fluid and/or tissue in the form of abscess fluid, infected materials, etc.	VacLok AT Vacuum Syringe is used to inject fluids into, or withdraw fluids from the body. It can also be used in cases where a vacuum syringe is preferred (e.g. thrombus, abscess fluid, bile, urine, etc.).	Substantially equivalent. The indications for use for the Removal System Large Bore 60 cc Syringe is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the performance of the device. The subject and predicate device have the same intended use.
Design	Standard piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting moveable plunger and plunger seal. Contains twist-to-lock plunger to maintain the retracted position of the plunger. Fitted with a large bore Toomey tip adapter that acts as a quick-release connector.	Standard piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting moveable plunger and tip/seal. Variable camlock technology maintains the retracted position of the plunger. Fitted with male luer lock connector.	Similar in design. The subject device met all design verification and validation acceptance criteria. The minor design differences between the subject and predicate device do not raise new or different questions of safety or effectiveness.
Device Description	The Removal System Large Bore 60 cc Syringe is a general piston syringe constructed using a barrel, plunger, plunger seal, and large bore Toomey tip adapter that acts as a quick-release connector. The quick-release connector is compatible with the Removal System Catheters' sideport connector to establish an airtight seal. The twist-to-lock plunger with barrel tabs maintains the retracted position of the plunger.	The VacLok AT Vacuum Syringe is a general piston syringe constructed using a barrel, plunger, piston seal, and locking mechanism. It is designed to lock in any position along the length of the barrel with the capability of holding a vacuum when the cam locking mechanism is engaged.	-
Barrel Material	Clear polycarbonate	Clear polycarbonate	Identical.
Plunger Material	ABS	ABS	Identical.
Seal Material	EPDM Rubber	Silicone	The Removal System Large Bore 60 cc Syringe materials are established medical device materials

			and have successfully passed ISO 10993-1:2018 biocompatibility testing as part of the final, finished device intended for marketing.
Operational Volume	60 mL	20 mL and 30 mL	The subject device met all design verification and validation acceptance criteria. The operatonal volume difference between the subject and predicate device do not raise new or different questions of safety or effectiveness.
Graduation	Printed with accurate graduation lines that are compliant with ISO 7886-1	Printed with accurate graduation lines that are compliant with ISO 7886-1	Identical.
Vacuum Lock Technology	Twist-to-lock plunger with barrel tabs	Variable camlock technology	Similar locking mechanism for vacuum source. The subject device and predicate device locking mechanism differs only in the number of locking positions along the barrel. The subject device contains one locking position at the operational volume of 60 mL, while the predicate device contains ninety locking positions along the barrel length. Both devices are locked and unlocked by twisting the plunger in the barrel. This does not raise new or different questions of safety or effectiveness.
Tip	Large bore Toomey tip adapter	Male luer lock	-
Principles of Operation	Manually operated by advancing and withdrawing the plunger within the barrel.	Manually operated by advancing and withdrawing the plunger within the barrel.	Identical.
Sterilization	EtO	EtO	Identical.
Shelf-life	6 months	Information not available	The subject device met all T=6 month accelerated aging design verification and validation acceptance criteria.
Single-use	Yes	Yes	Identical.

Summary of substantial equivalence

Biocompatibility

The following biocompatibility tests were completed to satisfy ISO 10993-1 requirements for the subject device:

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

The passing results demonstrate that the subject device meets the biological safety requirements per ISO 10993-1.

Sterilization

The Removal System 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 Removal System Large Bore 60 cc Syringe to the predicate device and to support the indications for use. These tests included:

Performance Tests

- Packaging Inspection
- Leak Testing - Syringe to Quick-Connect Adapter
- Vacuum Testing - Syringe to Quick-Connect Adapter
- Air Leakage
- Simulated Pus Analog Removal
- Tensile Testing - Large Bore Syringe to Connector
- General, ISO 7886-1, Clause 6.1
- Limits for Acidity or Alkalinity, ISO 7886-1, Clause 6.2 & Annex A
- Limits for Extractable Metals, ISO 7886-1, Clause 6.3 & Annex A
- Lubricant, ISO 7886-1, Clause 7 (Paragraph 1)
- Tolerance on Graduated Capacity, ISO 7886-1, Clause 8
- Scale, ISO 7886-1, Clause 9.1
- Numbering of Scales, ISO 7886-1, Clause 9.2
- Overall Length of Scale, ISO 7886-1, Clause 9.3
- Position of Scale, ISO 7886-1, Clause 9.4
- Barrel Flanges, ISO 7886-1, Clause 10.2
- Design, ISO 7886-1, Clause 11.1
- Position of Nozzle on End of Barrel, ISO 7886-1, Clause 12.2
- Nozzle Lumen, ISO 7886-1, Clause 12.3
- Freedom from Liquid Leakage Past Plunger, guided by ISO 7886-1, Clause 13.2 & Annex D
- Freedom from Air Leakage Past Plunger, ISO 7886-1, Clause 13.2 & Annex B

- Force to Operate the Piston, ISO 7886-1, Clause 13.3 & Annex E
- Fit of Stopper/Plunger in Barrel, ISO 7886-1, Clause 13.4
- Particulate Matter

Leveraged Performance Tests

- Pouch Seal Visual Inspection (K191368 and K231848)
- Bubble Leak (K231848)
- Dye Penetration (K231848)
- Pouch Peel, Seal Strength (K231108)
- Packaging Usability Evaluation for Aseptic Presentation (K230494)
- Vacuum Testing – Large Bore Syringe (K191710)
- Simulated Use, Tensile – Large Bore Syringe (K191710)

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications.

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

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

Conclusion

The Removal System Large Bore 60 cc Syringe has the same intended use as the predicate. Non-clinical performance data show that the different technological characteristics between the devices do not raise any new or different questions of safety or effectiveness and support the Removal System Large Bore 60 cc Syringe's substantial equivalence to the predicate device.