DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 27, 2017

Merit Medical Systems, Inc.
Ms. Angela Brady
Senior Regulatory Affairs Specialist
1600 W Merit Parkway
South Jordan, Utah 84095

Re: K163597
Trade/Device Name: Merit VacLok™ AT Vacuum Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: PUR
Dated: July 25, 2017
Received: July 26, 2017

Dear Ms. Angela Brady:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark S. Fellman -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163597

Device Name
VacLok™ AT Vacuum Syringe

Indications for Use *(Describe)*
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.).

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

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-4818
	Fax Number:	(801) 316-4878
	Contact Person:	Ms. Angela Brady
	Date Prepared:	December 20, 2016
	Registration Number:	1721504
Subject Device	Trade Name:	VacLok™ AT Vacuum Syringe
	Common/Usual Name:	Piston Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Product Code:	PUR
	21 CFR §:	880.5860
	Review Panel:	General Hospital
Predicate Device	Trade Name:	Welmed Hypodermic Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Product Code:	FMF
	21 CFR §:	880.5860
	Premarket Notification:	K070936
	Manufacturer:	Welmed, Inc.
Reference Device	Trade Name:	VacLok Syringe
	Classification Name:	Syringe, Piston
	Regulatory Class:	2
	Product Code:	FMF
	21 CFR §:	880.5860
	Premarket Notification:	K994253
	Manufacturer:	Merit Medical Systems, Inc.
Device Description	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.	
Indications for Use	The 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.). The Indications for Use statement for the VacLok™ AT Vacuum 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. Both the subject and predicate devices have the same intended use to inject fluids into, or withdraw fluids from, the body, as stated in 21 CFR 880.5860.

Comparison to Predicate Device

The proposed VacLok™ AT Vacuum Syringe incorporates the same intended use, as well as similar materials, design and principle of operation as the predicate Welmed Hypodermic Syringe. The subject device is substantially equivalent to the predicate device.

Attribute	Subject Device – VacLok™ AT Vacuum Syringe	Predicate Device – Welmed Hypodermic Syringe
Design	Standard piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip/seal. Fitting offered with male luer lock connector.	Standard piston syringe constructed with a clear hollow barrel into which is inserted a closely fitting movable plunger and tip/seal. Fitting offered with male luer lock connector.
Material	The barrel is constructed from clear polycarbonate; the plunger from ABS material; the seal is made of silicone material	The barrel is constructed from clear polycarbonate. The plunger/piston seal unknown
Principle of Operation	Manually operated by advancing and withdrawing the plunger within the barrel.	Manually operated by advancing and withdrawing the plunger within the barrel.
Operational Volume	Operational volume of 20 and 30 mL.	Operational volume of 3, 5, 10, 20, 30 and 60 mL.
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.
Intended Use	General purpose fluid injection and aspiration from the body, as outlined in 21 CFR 880.5860.	General purpose fluid injection and aspiration from the body, as outlined in 21 CFR 880.5860.

The reference device supports the vacuum technology for the subject device.

Reference Device Comparison

Attribute	Subject Device – VacLok™ AT Vacuum Syringe	Reference Device – VacLok Syringe
Vacuum Technology	Variable camlock technology	Fixed stop position technology

FDA guidance and recognized consensus standards have been established for Piston Syringes under FDA Product Code FMF and 21 CFR 880.5860. A battery of tests was performed based on the requirements of the below recognized consensus standards and guidance, as well as biocompatibility, sterilization, and packaging standards and guidance. Conformity to these standards demonstrates that the proposed VacLok™ AT Vacuum Syringe met the standards' established acceptance criteria for the device.

Performance Data

- ISO 7886-1:1993, *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use [Including Technical Corrigendum 1 (1995)]*
- ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*
- ISO 11135:2014*, Sterilization of health care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices*
- ISO 10993-7:2008, *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals*
- AAMI TIR 28:2009*, Product adoption and process equivalency for ethylene oxide sterilization*
- ISO 11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)]*
- ASTM D4169-14: 2014, *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM F1980-07:2007, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (Reapproved 2011)*
- ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing*
- ISO 10993-1:2009, *Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process [Including: Technical Corrigendum 1 (2010)]*

Performance Data cont'd

- ISO 10993-4:2002 (Amd.1:2006), *Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood [Including: Amendment 1(2006)]*
- ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ASTM F756-08:2008, *Standard Practice for Assessment of Hemolytic Properties of Materials*
- AAMI/ANSI ST72:2011, *Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing*
- United States Pharmacopeia 37, National Formulary 32, 2014 *<151> Pyrogen Test*
- FDA Guidance Use of International Standard ISO 10993-1, *'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, June 2016*
- FDA Guidance Document, *Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes, April 1993*
- FDA Guidance*, The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, March 1998*
- FDA Guidance, *Recognition and Use of Consensus Standards, September 2007*

Performance Bench Testing

The VacLok™ AT Vacuum Syringe complies with the FDA recognized consensus standards ISO 7886-1 and ISO 594-2, as outlined within this submission. Results of the testing demonstrate that the subject device met the acceptance criteria sufficient for its intended use. Testing included the following from these standards:

ISO 7886-1	
Cleanliness	Graduation Scale
Limits for acidity or alkalinity	Barrel
Limits for extractable metals	Piston/Plunger Assembly
Lubricant	Nozzle
Tolerance on Graduation Capacity	Performance – Freedom from air and liquid leakage past piston
ISO 594-2	
Gauging	Unscrewing torque
Liquid leakage	Ease of assembly
Air leakage	Resistance to overriding
Separation force	Stress cracking
Vacuum Performance Testing	
Air Leakage (Annex B of ISO 7886-1)	Vacuum Hold (Annex B of ISO 7886-1, 2 minutes)

Performance Data cont'd	**Biocompatibility testing** Biocompatibility evaluation for the VacLok™ AT Vacuum Syringe was conducted in accordance with ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", and the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," June 2016. Testing included the following: • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Hemolysis • USP Physicochemical The VacLok™ AT Vacuum Syringe is considered an externally communicating device with indirect blood contact for a duration of less than 24 hours.
Summary of Substantial Equivalence	Based on the intended use, materials, design, and performance testing, the VacLok™ AT Vacuum Syringe meets the requirements that are considered essential for its intended use and is considered substantially equivalent to the predicate device, the Welmed Hypodermic Syringe, K070936.