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

January 25, 2017

Merit Medical Systems, Inc.
Ileana Davis
Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K162988
Trade/Device Name: PreludeSYNC Radial Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 22, 2016
Received: December 30, 2016

Dear Ms. Davis:

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" (21 CFR 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K162988

Device Name
PreludeSYNC Radial Compression Device

Indications for Use *(Describe)*
The PreludeSYNC is a compression device used to assist in gaining hemostasis of arterial percutaneous access sites.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5.0 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4187
	Fax Number:	(801) 316-4065
	Contact Person:	Ileana Davis, Regulatory Affairs Specialist
	Date Prepared:	26 October 2016
	Registration Number:	1721504
Subject Device	Trade Name:	PreludeSYNC™ Radial Compression Device
	Common/Usual Name:	Radial Compression Device
	Classification Name:	Vascular Clamp
	Regulatory Class:	II
	Product Code:	DXC
	21 CFR §:	870.4450
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	Vasc™ Band Hemostat
	Classification Name:	Vascular Clamp
	Premarket Notification:	K142359
	Manufacturer:	Lepu Medical Technology (Beijing) Co., Ltd.
	This predicate has not been subject to a design-related recall in the US.	
Device Description	The PreludeSYNC™ Radial Compression Device is a sterile, single use disposable device used to assist in gaining and maintaining hemostasis of the radial and ulnar artery following catheterization procedures. It consists of a soft wristband with a secure hook and loop fastener and a clear curved backer plate that provides optimal visualization of the puncture site and ease of placement. The inflatable bulb delivers adjustable compression of the puncture site. A check valve and tubing allow for easy inflation and deflation with the accompanying 20ml syringe inflator. PreludeSYNC is available in a variety of graphic designs and in two band sizes: regular (24cm) and long (29cm).	
Indications for Use	The PreludeSYNC is a compression device used to assist in gaining hemostasis of arterial percutaneous access sites. The Indications for Use statement for the PreludeSYNC 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 safety and effectiveness of the device relative to the predicate. Both the subject	

	and predicate devices have the same intended use of providing compression to assist hemostasis of percutaneous access sites.
Comparison to Predicate Device	The technological characteristics of the subject PreludeSYNC™ Radial Compression device are substantially equivalent to those of the predicate Vasc™ Band Hemostat. At a high level, the subject and predicate devices are based on the following same technological elements: • Clinical use • Labeling • Basic design • Principle of operation • Performance • Band sizes The following technological difference exists between the subject and predicate devices: • Materials
Performance Data	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject PreludeSYNC™ Radial Compression Device was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 594-1 – Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements • ISO 594-2 – Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings • ISO 2233:2001 – Packaging – Complete, filled transport packages and unit loads – Conditioning for testing • ISO 11607-1:2006 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems • ASTM D4169-09 – Standard Practice for Performance Testing of Shipping Containers and Systems • ASTM F1980-11 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices • 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 10993-1:2009 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009 – Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity • ISO 10993-7:2008 – Biological evaluation of medical devices – Part 7: Ethylene oxide residuals

- 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

The following performance data were provided in support of the substantial equivalence determination:

Performance Testing – Bench

- Dimensions
- Tensile of Joints
- Submerged Air Leak Test
- Inflation Bulb Burst Test
- Hook-and- Loop Detachment Test
- Integrity Test
- Band Absorbency
- Backer Plate Transparency
- Ink Adherence
- Simulated Use

Biocompatibility testing

The biocompatibility evaluation for the PreludeSYNC™ Radial Compression Device was conducted in accordance with the FDA Guidance Document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'" June 16, 2016, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity

Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject PreludeSYNC™ Radial Compression Device meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Vasc™ Band Hemostat, K142359.