July 22, 2026

Merit Medical Systems, Inc.
Frank Sauz
Platform Regulatory Specialist II
1600 W. Merit Pkwy.
South Jordan, Utah 84095

Re: K262086
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: June 19, 2026
Received: June 22, 2026

Dear Frank Sauz:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2026.07.22 15:06:18 -06'00'

Katherine Trivedi
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262086

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.

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Merit PreludeSYNC™ Radial Compression Device

510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4789
	Fax Number:	(801) 208-4789
	Contact Person:	Frank Sauz
	Date Prepared:	06/19/2026
	Registration Number:	1721504
Subject Device	Trade Name:	PreludeSYNC™ Radial Compression Device
	Common/Usual Name:	Merit Radial Compression Device
	Classification Name:	Vascular clamp
	Regulatory Class:	II
	Product Code:	DXC
	21 CFR §:	870.4450
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	PreludeSYNC™ Radial Compression Device
	Classification Name:	Vascular clamp
	Premarket Notification:	K162988
	Manufacturer:	Merit Medical Systems, Inc.
	This predicate has not been subject to a design-related recall	
Reference Device	Trade Name:	StatSeal Disc
	Classification Name:	Unclassified
	Premarket Notification:	K130324
	Manufacturer:	Merit Medical Systems, Inc.
	This reference device has not been subject to a design-related recall	
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. There is no change in the Indications for Use Statement from the predicate to the subject device.	

Comparison to Predicate Device	The subject PreludeSYNC™ Radial Compression Device has similar technological characteristics as the predicate PreludeSYNC™ Radial Compression Device. The comparison between the subject device and predicate devices is based on the following: • Same Clinical use • Same Indications for use • Same Basic Design • Same fundamental technology/principle of operation • Same sterilization methods • Same intended use No differences in fundamental technology or principle of operation. The only difference is related to labeling (additional instructions for device placement and removal). These differences are limited to labeling updates and do not alter the intended use, design, materials, or fundamental scientific technology of the device.
Performance Data	No performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act for this device type. The PreludeSYNC™ Radial Compression Device has been previously evaluated through verification and validation testing to demonstrate that it meets its design specifications and performs as intended. The labeling-only modification described in this submission does not impact the device design, materials, performance specifications, or intended use. A risk-based assessment was conducted to evaluate the impact of the labeling modification. The assessment determined that the changes to the Instructions for Use (IFU) do not affect critical tasks or introduce new use-related risks. The IFU updates were further evaluated through clinician-based validation to confirm that the modified instructions support safe and clinically acceptable use of the device. Results from this evaluation met predefined acceptance criteria and demonstrated that the changes are acceptable for clinical use. Based on this evaluation, no additional performance or design validation testing was required. The previously established verification and validation data, together with the IFU validation results, support that the PreludeSYNC™ Radial Compression Device continues to meet all pre-determined acceptance criteria and that the labeling-only modification does not adversely impact device safety or performance.

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, PreludeSYNC™ Radial Compression Device K162988.