5.0 510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4789 (801) 253-6919 Susan Christensen March 15, 2018 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	PreludeSYNC DISTAL™ Radial Compression Device Radial Compression Device Vascular Clamp II DXC 870.4450 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	PreludeSYNC™ Radial Compression Device Radial Compression Device K162988 Merit Medical Systems, Inc. The predicate has been the subject of a design-related recall, reference Z-1766-2017
Reference Device	No reference devices were used in this submission.	
Device Description	The PreludeSYNC DISTAL™ Radial Compression Device is a sterile, single use disposable device used to assist in gaining and maintaining hemostasis of the radial artery following catheterization procedures. It consists of a soft wristband and thumb saddle strap with secure hook and loop fasteners. The band delivers adjustable compression of the puncture site with an inflatable balloon, and a check valve for easy inflation and deflation with the accompanying 10mL syringe inflator. A clear curved backer plate provides optimal visualization of the puncture site and ease of placement. PreludeSYNC DISTAL is available in a variety of graphic designs and a right or left-hand configuration.	
Indications for Use	The PreludeSYNC DISTAL™ is a compression device used to assist in gaining hemostasis of arterial percutaneous access sites.	

Comparison to Predicate Device	The design and technological characteristics of the subject PreludeSYNC DISTAL Radial Compression Device are substantially equivalent to those of the predicate PreludeSYNC. The subject device has the same materials and use as the predicate device. The main difference between the subject and the predicate device is the design of the PreludeSYNC DISTAL is slightly different (including addition of a thumb saddle strap and modified syringe inflator components) with different dimensions of the backer plate, straps, and balloon. The comparison between the subject and the predicate devices is based on the following: • Same Clinical use • Same Intended use • Same Indications for use • Same Materials • Similar design • Same Sterilization methods • Same Labeling and packaging • Same Fundamental technology/principle of operation
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 DISTAL Radial Compression Device was conducted based on the risk analysis and based on the requirements of the following international standard: • *ISO 80369-7: 2016, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications* • 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 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals* • ISO 2233:2000, *Packaging – complete, filled transport packages and unit loads – conditioning for testing* • *ASTM D4169:2016, Standard practice for performance testing of shipping containers and systems*

Safety & Performance Data	The following tests were performed to demonstrate there were no unacceptable risks associated with the changes made to the device: <u>Performance Testing-Bench</u> • Bubble Emission - Packaging • Visual Inspection - Packaging • Adapted Connector Torque • Dimensions - Band Sizing Verification • Side Load and Leak Test • Indicator Mark Adherence • Hook and Laminate Integrity Test • Balloon Burst Test • Adapted Cap to Valve Attachment • Tensile Test - Hook and Loop • Tensile Test - Band to Backer Plate • Band Compliance • Simulated Use <u>Biocompatibility Testing</u> All materials of the subject device (excluding the colorant in the plunger) are used in the legally marketed predicate PreludeSYNC with the same intended use, patient contact, processing and sterilization methods. Therefore, no further biocompatibility testing is required for these materials. The plunger in the inflation syringe is categorized as having no direct or indirect contact with the human body. Based on the contact categorization of the plunger component, biocompatibility testing is not required. The PreludeSYNC DISTAL is categorized as a Surface Device with Breached or Compromised Surface Contact for a Limited (≤ 24 hours) Duration The results of the testing demonstrated that the subject PreludeSYNC DISTAL met the predetermined acceptance criteria applicable to testing the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject PreludeSYNC DISTAL Radial Compression Device raises no new questions of safety or effectiveness compared to the predicate device and is substantially equivalent to the predicate device, the PreludeSYNC K162988 manufactured by Merit Medical Systems, Inc.