Merit Medical System, Inc.
Siobhan King
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K212817
Trade/Device Name: Merit Siege Vascular Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: November 5, 2021
Received: November 12, 2021

Dear Siobhan King:

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. 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 located 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.

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

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 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,

Misti Malone, PhD
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212817

Device Name
Merit Siege Vascular Plug

Indications for Use *(Describe)*
The Siege Vascular Plug is indicated for arterial embolization in the peripheral vasculature.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(+353) 91 703700 (Ext. 3061)
	Fax Number:	(+353) 91 680104
	Contact Person:	Mark Mullaney
	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
	Address:	Parkmore Business Park Parkmore, Galway, Ireland
	Telephone Number:	(+353) 91 703700 (Ext. 3052)
	Fax Number:	(+353) 91 680104
	Contact Person:	Siobhan King
	Date of Preparation:	31 August 2021
	Registration Number:	9616662
Subject Device	Trade Name:	Merit Siege Vascular Plug
	Common/Usual Name:	Vascular Device for promoting embolization
	Classification Name:	Vascular Embolization Device
Predicate Device	**Premarket Notification Predicate:**	
	Trade Name:	Dr. Amplatz Micro Plug
	Classification Name:	21 CFR 870.3300 Vascular Embolization Device
	Premarket Notification:	K182944
	Manufacturer:	KA Medical
	Premarket Notification Reference Device#1:	
	Trade Name:	Amplatzer® Vascular Plug (AVP)
	Classification Name:	21 CFR 870.3300 Vascular Embolization Device
	Premarket Notification:	K031810
	Manufacturer:	Abbott
	Premarket Notification Reference Device#2:	
	Trade Name:	Micro Vascular Plug System (MVP)
	Classification Name:	21 CFR 870.3300 Vascular Embolization Device

	Premarket Notification: K123803 Manufacturer: Medtronic **Premarket Notification Reference Device#3:** Trade Name: Micro Vascular Plug System (MVP) Classification Name: 21 CFR 870.3300 Vascular Embolization Device Premarket Notification: K133282 Manufacturer: Medtronic
Classification	Class II 21 CFR § 870.3300 Product code: KRD Division of Cardiovascular Devices
Intended Use	The Siege Vascular Plug is indicated for arterial embolization in the peripheral vasculature.
Device Description	The Siege™ Vascular Plug ("Device") is a self-expanding braided nitinol vascular occlusion implant that is supplied with components used for implantation. The Device has radiopaque marker bands attached to each end and a screw attachment for connection to a Delivery Wire. The Device is packaged collapsed within a Loader and attached to a 180cm Delivery Wire that is provided within a hoop dispenser. Touhy Borst Valves are provided for flushing and maintaining hemostasis. A Torque Device is provided for releasing the Device. The Siege™ Vascular Plug has been designed with a material, size, configuration and shape that allows introduction through recommended 0.027" inner diameter commercial microcatheters for the occlusion of blood vessels in the peripheral vasculature. The Siege™ Vascular Plug Devices are provided in four different diameters (3mm, 4mm, 5mm, 6mm) to treat different sized blood vessels in the peripheral vasculature. The Siege™ Vascular Plug is designed to be used under fluoroscopy for delivery and implantation in the peripheral vasculature. The main users of the device are physicians trained in vascular embolization.
	The subject Merit Siege™ Vascular Plug is substantially equivalent in its intended use/indications for use,

technology/principle of operation, materials and performance specification to the predicate KA Medical Micro Plug Set (K182944).

A comparison of the technological characteristics is summarized in the table below:

Comparison to Predicate

Device Characteristic	Subject Merit Siege™ Vascular Plug	Predicate KA Medical, Micro Plug Set (K182944)
510(k) #	K212817	K182944
Product Code	KRD	Same
Indications for Use/Intended Use	indicated for arterial embolization in the peripheral vasculature	Same
Components Supplied in the Sterile Package	• Siege Vascular Plug • Loader • Delivery Wire • Torque Device • Tuohy Borst Valves	• Micro Plug Device • Loader • Delivery Wire • Torque Device • Tuohy Borst Valves • Delivery Catheter
Component Construction Materials	**Plug** • Nitinol braid • Platinum-iridium radiopaque marker bands • 316 L Stainless Steel female threaded component at proximal end **Delivery Wire** • Nitinol ground core wire, stainless steel screw, stainless steel outer coil. **Tuohy Borst Valve** • Body and Cap – polycarbonate • Seal – silicone, blue • Washer - PTFE **Loader** • Rilsan (nylon) tubing with Vestamid hub and PTFE liner **Torque Device** • Polycarbonate cap, polypropylene body, brass collet **Delivery Catheter** • No longer supplied – compatible with commercially available 0.027” inner diameter microcatheters	**Plug** • Same **Delivery Wire** • Same **Tuohy Borst Valve** • Same **Loader** • Rilsan (nylon) tubing with Pebax hub, LDPE strain relief and PTFE liner **Torque Device** • Polybutylene Terephthalate (PBT) **Delivery Catheter** • Nylon, Pebax, Stainless steel braid, PTFE, Grilamed, platinum-iridium, Hydrophilic coating

Dimensions	**Siege Vascular Plug** Diameter sizes: 3,4,5 & 6 mm Construction: • 3 lobes • 2 braid layers - each layer is comprised of 72 wires with diameters of 0.0008 and/or 0.001 inches • Female threaded bushing 0.052" length • Markerband ID 0.016" Device Diameter / Device Length* 3 mm / 6.0 mm 4 mm / 5.2 mm 5 mm / 5.2 mm 6 mm / 5.2 mm *unconstrained – elongates when constrained with oversizing **Delivery Wire** • Reduction in OD to 0.022" outer HHS **Loader** • 0.026" ID with tapered distal tip geometry, length increased to 11.2" **Touhy Valve** • FLO40 **Torque Device** • 3 Part torque device **Delivery Catheter (not included)** Introduction through 0.027" inner diameter commercially compatible microcatheters up to 150 cm long is recommended.	**Micro Plug Set** Diameter sizes: 3,4,5 & 6 mm Construction: • 3 lobes • 2 braid layers - each layer is comprised of 72 wires with diameter of 0.001 inches • Female threaded bushing 0.047" length • Markerband ID 0.018" Device Diameter / Device Length* 3 mm / 5.2 mm 4 mm / 5.2 mm 5 mm / 5.2 mm 6 mm / 5.2 mm *unconstrained – elongates when constrained with oversizing **Delivery Wire** • OD 0.024" outer HHS **Loader** • 0.029" ID with chamfered distal tip geometry, length 8.75" **Touhy Valve** • Same **Torque Device** • 2 part torque device **Delivery Catheter included:** 2.9F, 125 cm long, .028-inch inner diameter with hydrophilic coating
Single Use	Yes	Same
Anatomical site	Peripheral vasculature	Same
Sterilization	Sterile/Ethylene Oxide SAL 10^{-6}	Same
Shelf Life	1 year	3 years
Pyrogenicity	Yes	Same
Packaging	Length of backing card, pouch and box designed to accommodate all components (except a microcatheter). Similar packaging but will be shorter in length to accommodate the removal	Length of backing card, pouch and box designed to accommodate all components and included catheter.

		of the catheter and will include a retention clip to anchor the delivery wire.	
	Principles of operation	The Delivery Wire with attached Siege Vascular Plug is transferred into a recommended 0.027" inner diameter commercially compatible microcatheter using the provided Loader. The Plug is advanced through a recommended microcatheter to the targeted position. The Siege Vascular Plug is advanced out of the microcatheter; the Siege Vascular Plug device self-expands recovering its pre-set shape and cross-sectionally occludes the vasculature. If Device position is unsatisfactory, the device can be repositioned or removed. If position is satisfactory, the Delivery Wire is rotated counterclockwise using the provided Torque Device to release the Siege Vascular Plug.	The Delivery Wire with attached Micro Plug Set Device is transferred into the Delivery Catheter using the provided Loader. The plug is advanced through the supplied Delivery Catheter to the targeted position. The Micro Plug Set Device is advanced out of the Delivery Catheter; the Micro Plug Set Device self-expands recovering the pre-set shape and cross-sectionally occludes the vasculature. If Device position is unsatisfactory, the Device can be repositioned, redeployed or removed. If position is satisfactory, the Delivery Wire is rotated counterclockwise using the provided Torque Device to release the Micro Plug Set Device.

Safety & Performance Tests

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. However, Vascular and Neurovascular Embolization Devices are subject to the Special Controls specified in "Vascular and Neurovascular Embolization Devices – Class II Special Controls Guidance Document for Industry and FDA Staff", issued on December 29, 2004. A battery of testing was conducted, on the subject Merit Siege™ Vascular Plug, in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence. The evaluations included performance testing, biocompatibility, sterilization, and animal studies.

Where appropriate, the tests were based on the requirements of the following documents:

FDA Guidance documents:

- *Vascular and Neurovascular Embolization Devices – Class II Special Controls Guidance Document for Industry and FDA Staff (December 29, 2004)*

- *Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol, Guidance for Industry and FDA Staff (July 09, 2021)*
- *Q3D(R1) Elemental Impurities – Guidance for Industry (March 2020)*
- *Applying Human Factors and Usability Engineering to Medical Devices to Optimize Safety and Effectiveness in Design (February 2016)*
- *MRI Compatibility Testing and Labelling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (May 2021)*
- *Select updates for Non-Clinical Engineering Tests and Recommended Labelling for Intravascular Stents and Associated Delivery Systems (August 2015)*

Recognized Standards

- ISO 10555-1:2013 Intravascular Catheters-Sterile and Single-use Catheters
- ISO 80369-7:2016 Small bore connectors for liquids and gases in healthcare applications – Part 7: connectors for intravascular or hypodermic applications
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications- Part 20: Common test methods
- ASTM F2005 – Standard Terminology for Nickel-Titanium Shape Memory Alloy
- ASTM F2004 – Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis
- ISO 14630:2012 Non-active surgical implants - General requirements
- ASTM F2129-19a Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small implants
- ASTM F3044-20 Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants
- ASTM G71-81 2014 Standard guide for conducting and evaluating galvanic corrosion tests in electrolytes
- ASTM F2052-15 Standard Test Method for the Measurement of Magnetically Induced Displacement Force on medical Devices in the Magnetic Resonance Environment
- ASTM F2182-19e Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the
  Magnetic Resonance Environment

- ASTM F2119-07(2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM D4169-16 Standard Practice For Performance Testing Of Shipping Containers And Systems
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F88 / F88M - 15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096 - 11(2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D4332-14 Standard Practice for Conditioning Containers. Packages, or Packaging Components for Testing
- AAMI TIR28:2016 Product adoption and process equivalence for ethylene oxide sterilization
- ISO 2233:2001 Packaging – Complete, filled transport packages and unit loads – Conditioning for testing
- ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- 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 10993-1:2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, and the FDA Guidance for Industry, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

The subject Merit Siege™ Vascular Plug was compared to the predicate device for various performance attributes that support substantial equivalence of the device.

The following testing was successfully completed:

<u>Performance Testing</u>

- Simulated Use - Loader Flushing, Device Handoff, Device Advancement, Deployment, Apposition, Recapture, Redeployment, Device Release
- Set Strength

	• Delivery Wire Proximal Weld Strength
	• Loader Fluid Leakage Under Pressure
	• Loader Hub to Loader Tube Peak Tensile Force
	• Luer Testing
	• Fatigue testing
	• Nickel leach
	• Radial Force
	• Migration resistance
	• Nitinol Austenite Finish Temperature
	• MRI Testing
	• Corrosion Testing
	• Size Designation
	• Packaging
	  ○ Visual
	  ○ Dye penetration testing
	  ○ Bubble Leak Test
	  ○ Seal peel strength
	  ○ Burst Test
	• Sterilization
	• Shelf life
	• Biocompatibility
	• GLP Animal Study
	  ○ Acute performance
	  ○ Chronic performance
	  ○ Tissue response
	
	Clinical testing was not required for the determination of substantial equivalence.
	
	All test results were comparable to the predicate devices and the subject Merit Siege™ Vascular Plug met the pre-determined acceptance criteria. This has demonstrated that the subject device is substantially equivalent to the predicate device, K182944.

Summary of Substantial Equivalence	Based on the Indications for Use, design, safety and performance testing, the subject Merit Siege™ Vascular Plug meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, KA Medical, Micro Plug Set (K182944).