May 2, 2024

Merit Medical Systems, Inc.
James Kenny
Principal Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K240261
Trade/Device Name: Siege Vascular Plug (SVP2.5-0.021); Siege Vascular Plug (SVP4-0.021); Siege Vascular Plug (SVP6-0.027)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: January 31, 2024
Received: April 8, 2024

Dear James Kenny:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Misti L. Malone -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240261

Device Name
Siege Vascular Plug (SVP2.5-0.021);
Siege Vascular Plug (SVP4-0.021);
Siege Vascular Plug (SVP6-0.027)

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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510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
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	Telephone Number:	(+353) 91 651 560
	Fax Number:	(+353) 91 680 104
	Contact Person:	James Kenny
	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
	Address:	Parkmore Business Park Parkmore, Galway, Ireland
	Telephone Number:	(+353) 91 703 761
	Fax Number:	(+353) 91 680 104
	Contact Person:	James Kenny
	Date of Preparation:	26 January 2024
	Registration Number:	9616662
Subject Device	Trade Name:	Siege™ Vascular Plug
	Common/Usual Name:	Vascular embolization plug
	Class:	II
	Product code:	KRD
	Classification Name:	Device, Vascular, For Promoting Embolization
	Regulation Number:	21 CFR 870.3300
	Regulation Medical Specialty	Cardiovascular
Predicate Device	Trade Name:	Siege™ Vascular Plug
	Class:	II
	Product code:	KRD
	Classification Name:	Device, Vascular, For Promoting Embolization
	Regulation Number:	21 CFR 870.3300
	Regulation Medical Specialty	Cardiovascular
	Premarket Notification:	K212817
	Manufacturer:	Merit Medical Systems, Inc.

Reference Devices	**Reference Device#1:**	
	Trade Names:	Micro Vascular Plug System (MVP) MVP-3Q, MVP-5Q, MVP-7Q
	Premarket Notification:	K123803, K133282, K150108
	Reference Device#2:	
	Trade Name:	Amplatzer Vascular Plug (AVP)
	Premarket Notification:	K031810
	Reference Device#3:	
	Trade Name:	Micro Plug Set
	Premarket Notification:	K182944
Device Description	The subject Siege Vascular Plug ("Device") is a self-expanding braided Nitinol vascular embolization 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 the Delivery Wire. The Device is packaged collapsed within a Loader and attached to a 225 cm Delivery Wire that is provided within a hoop dispenser. The Delivery Wire has a lubricious, hydrophilic coating at its distal end (approximately 26.5cm long). A Tuohy Borst Valve is provided for flushing and maintaining hemostasis; a Torque Device is provided for releasing the Device; a Non-Vented Luer Cap is provided for device preparation. The subject Siege Vascular Plug has been designed with a material, size, configuration, and shape that allows introduction through recommended 0.021" or 0.027" inner diameter commercial microcatheters for the embolization of arterial blood vessels in the peripheral vasculature. The Siege Vascular Plug Devices are provided in three different outer diameters (4.5 mm, 6.5 mm, 8.5 mm) to treat different artery diameter ranges (1.5 – 2.5 mm, 2.5 – 4 mm, 4 – 6 mm) in the peripheral vasculature. The subject Siege Vascular Plug is designed to be used under fluoroscopy for delivery and implantation in the peripheral vasculature. The main users are physicians trained in standard endovascular techniques.	
Intended Use	The Siege Vascular Plug is intended for therapeutic embolization to reduce or obstruct blood flow.	
Indications for Use	The Siege Vascular Plug is indicated for arterial embolization in the peripheral vasculature.	

Comparison to Predicate

The subject Siege Vascular Plug is substantially equivalent in its intended use/indications for use, technology/principle of operation, materials, and performance specification to the predicate Siege Vascular Plug [K212817].

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

Device Characteristic	Subject Siege Vascular Plug	Predicate Siege Vascular Plug
510(k) #	To be assigned	K212817
Product Code	KRD	KRD
Intended Use/ Indications for Use	The Siege Vascular Plug is indicated for arterial embolization in the peripheral vasculature. The Siege Vascular Plug is intended for therapeutic embolization to reduce or obstruct blood flow.	Indicated for arterial embolization in the peripheral vasculature.
Components Supplied in the Sterile Package	• Siege Vascular Plug • Loader • Delivery Wire • Torque Device • Tuohy Borst Valve • Non-Vented Luer Cap	• Siege Vascular Plug • Loader • Delivery Wire • Torque Device • Tuohy Borst Valves (2)
Component Construction Materials	**Plug** • Nitinol braid • Platinum-Iridium radiopaque marker bands • Platinum-Iridium female threaded component at proximal end **Delivery Wire** • Nitinol ground core wire, stainless steel screw, gold plated tungsten coil, polymer (Pellethane) jacket with a lubricious, hydrophilic, coating applied at its distal end (26.5 +/- 1.5 cm long)	**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. No lubricious coating.

		Tuohy Borst Valve • Body, Housing, Nut and Cap – polycarbonate • Seal – silicone rubber, blue • O-ring – silicone rubber • Washer & Back-Up Ring – PTFE • Adhesive • Lubricant – Silicone Oil **Loader** • High Density Polyethylene (HDPE) tubing with polyolefin heat shrink **Torque Device** • Polycarbonate cap, polypropylene body, brass collet **Non-Vented Luer Cap** • Polycarbonate • Colorant, Polycarbonate, Red	**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
Dimensions		**Siege Vascular Plug** Diameter sizes: 4.5, 6.5, & 8.5 mm Construction: • 2 lobes • 2 or 3 braid layers - each layer is comprised of 64 and/or 72 wires with diameters of 0.0008 and/or 0.001 inches • Female threaded bushing with either 0.065 or 0.080” length • Markerband ID 0.016” Device Diameter / Device Length* 4.5 mm / 6.4 mm 6.5 mm / 7.3 mm 8.5 mm / 7.8 mm *unconstrained – elongates when constrained with oversizing **Delivery Wire** • Outer Diameter: 0.022” and 0.018” • Length: 225 cm	**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** • Outer Diameter: 0.022” • Length: 180 cm

	Loader • Inner Diameter: 0.023" & 0.028" • Length: 14" **Touhy Valve** • FLO50 **Torque Device** • 3 Part torque device	**Loader** • Inner Diameter: 0.026" ID • Length: 11.2" **Touhy Valve** • FLO40 **Torque Device** • 3 Part torque device
Catheter Compatibility	**Delivery Catheter (not included)** Introduction through 0.021" or 0.027" inner diameter commercially compatible microcatheters up to 175 cm long is recommended.	**Delivery Catheter (not included)** Introduction through 0.027" inner diameter commercially compatible microcatheters up to 150 cm long is recommended.
Use	Single Use	Single Use
Anatomical Site	Peripheral vasculature	Peripheral vasculature
Sterilization	Sterile/Ethylene Oxide SAL 10^{-6}	Sterile/Ethylene Oxide SAL 10^{-6}
Shelf Life	6-months	3-years
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic
Packaging	Pouch and generally square box designed to accommodate all components (except a microcatheter). Accessory pouch for torque device, Tuohy Borst Valve and non-vented luer cap. Hoop dispenser to contain delivery wire, loader and plug with a retention clip to anchor the delivery wire.	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 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 0.021" or 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	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

		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.	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.

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 in December 2004. A battery of testing was conducted, on the subject 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:

Safety & Performance Tests

The following is a list of all testing that was successfully completed on the subject Siege Vascular Plug:

<u>Performance Non-Clinical Testing</u>

1. Simulated Use
2. Set (Tensile) Strength
3. Loader Heat Shrink Tensile
4. Fatigue Testing
5. Nickel Leach
6. Radial Force
7. Nitinol Austenite Finish Temperature
8. MRI Compatibility
9. Corrosion Testing
10. Dimensional Testing/Size Designation
11. Particulate Testing
12. Radiopacity Testing
13. Packaging
14. Sterilization

	15. Pyrogenicity 16. Shelf life 17. Biocompatibility 18. GLP Animal Study The GLP animal study was conducted to evaluate the acute and chronic safety, performance and handling of the subject Siege Vascular Plug as compared to a commercially available Reference Device in the peripheral arteries of a porcine model. Clinical testing was not required for the determination of substantial equivalence. All test results were comparable to the predicate Siege Vascular Plug and the subject Siege Vascular Plug met the predeterminded acceptance criteria. This demonstrated that the subject Siege Vascular Plug is substantially equivalent to the predicate Siege Vascular Plug.
Summary of Substantial Equivalence	Based on the comparisons noted, the subject Siege Vascular Plug meets the requirements for its intended use and is substantively equivalent to the predicate Siege Vascular Plug [K212817] also manufactured by Merit Medical Systems, Inc.