December 21, 2023

Merit Medical Systems, Inc.
% Yves Wong
Regulatory Affairs Specialist
Biosphere Medical, S.A.
Parc des Nations - Paris Nord 2
383 rue de la Belle Etoile
Roissy-en-France, 95700
France

Re: K233813
Trade/Device Name: Bearing nsPVA Express™
Regulation Number: 21 CFR§ 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: II
Product Code: NAJ, KRD
Dated: November 30, 2023
Received: November 30, 2023

Dear Yves Wong:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K233813

Device Name
Bearing nsPVA Express™

Indications for Use *(Describe)*
Bearing nsPVA Particles are used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

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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"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 703761
	Contact Person:	Mark Mullaney
	Registration Number:	1721504
	Correspondent Name:	Merit / Biosphere Medical, S.A.
	Address:	Parc des Nations – Paris Nord 2, 383 rue de la Belle Etoile 95700 Roissy-en-France, France
	Telephone Number:	+33 1 48 17 48 23
	Fax Number:	+33 1 49 38 02 68
	Contact Person:	Yves Wong
	Date of Preparation:	December 19, 2023
	Registration Number:	9615728
Subject Device	Trade Name:	Bearing nsPVA Express™
	Common/Usual Name:	Polyvinyl Alcohol Embolic Microspheres
	Class:	II
	Product code:	NAJ (Agents, Embolic, For Treatment of Uterine Fibroids) KRD (Device, Vascular, For Promoting Embolization)
	Classification Name:	Vascular Embolization Device
	Regulation Number:	21 CFR 870.3300
	Manufacturer:	Merit Medical Systems, Inc.
Predicate Device	Trade Name:	Bearing™ nsPVA Embolization Particles
	Premarket Notification:	K130259
	Manufacturer:	Merit Medical Systems, Inc.
	The predicate device has not been subject to any design-related recall.	

510(k) Summary

Device Description

Bearing nsPVA particles are irregularly-shaped, hydrophilic, non-resorbable particles made of 100% crosslinked poly(vinyl alcohol).
These embolization particles are intended to provide vascular occlusion or reduction of blood flow within target vessels upon placement through a catheter.

The particles of the subject device, the Bearing nsPVA Express, are provided sterile and for single use in a 20 mL polycarbonate syringe with a luer-lock connector, individually packaged in a sterile foil peel pouch.

Bearing nsPVA particles are calibrated and available in 7 size ranges (see table below) to enable the physician to choose depending on the diameter of the vessel to be embolized. Each syringe contains 100 mg of Bearing nsPVA particles.

Reference Code	Particle Size (µm)	Packaging Color Code
S100EP	45-150	Yellow
S200EP	150-250	Purple
S300EP	250-355	Dark Blue
S400EP	355-500	Green
S600EP	500-710	Orange
S800EP	710-1000	Light Blue
S1100EP	1000-1180	Red

Indications For Use

Bearing nsPVA is used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

Comparison to Predicate

Device & Predicate Device(s):	K233813	K130259	**Comment**
Device & Predicate Device(s):	Bearing nsPVA Embolization Particles in syringe	Bearing nsPVA Embolization Particles in vial	Similar
Indications	Bearing nsPVA is used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.	Bearing nsPVA is used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.	Same
Shape of particle	Irregular	Irregular	Same
Particle size (µm)	45-150 150-250 250-355 355-500 500-710 710-1000 1000-1180	45-150 150-250 250-355 355-500 500-710 710-1000 1000-1180	Same
Delivery Catheter Minimum Inner Diameter (inches)	0.020 For particles size (µm): 45-150, 150-250, 250-355, 355-500	0.020 For particles size (µm): 45-150, 150-250, 250-355, 355-500	Same
	0.024 For particles size (µm): 500-710	0.024 For particles size (µm): 500-710	Same
	0.027 For particles size (µm): 710-1000	0.027 For particles size (µm): 710-1000	Same
	0.040 For particles size (µm): 1000-1180	0.040 For particles size (µm): 1000-1180	Same
Packaging	Sealed polycarbonate syringe within peel away pouch	Sealed glass vial within peel away pouch	Different
Sterilization	Gamma radiation	Gamma radiation	Same
Shelf Life	12 months	36 months	Different

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The subject device, Bearing nsPVA Express™, is packaged in a polycarbonate syringe and the predicate device, Bearing nsPVA Embolization Particles, are packaged in a glass vial. Both devices have the same intended use, and use the same embolization particle components and materials, with the same sizes available. The subject device has a 12 month shelf life while the predicate device has a 3 year shelf life. However, the differences do not raise different questions of safety and effectiveness for the subject device.

Safety & Performance Tests

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

- **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"
- **FDA Guidance** – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices (December 29, 2004)
- **FDA Guidance** – "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile" – January 2016
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

The following is a list of all testing that was successfully completed to support the determination of substantial equivalence.

<u>Sterilization Validation</u>

Bearing nsPVA Express are provided sterile and also labeled "non-pyrogenic." The subject device is sterilized by gamma radiation. The following testing was performed:

- Sterilization validation was completed to a sterility assurance level (SAL) of 10^{-6} per the following standards:
  - ISO 11137-2:2013/Amd1:2022 – *Sterilization of Health Care Products – Radiations – Part 2: Establishing the sterilization dose*.
  - ISO 11737-1: 2018-01 [Including AMD1:2021] *Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]*.

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- ISO 11737-2 Third edition 2019-12 *Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

- Pyrogenicity
  - The Bearing nsPVA Express underwent routine pyrogen testing for each lot, utilizing the Limulus Amebocyte Lysate (LAL) test in accordance with USP General Chapter <85>, Bacterial Endotoxins Test, and successfully met the acceptance criteria.

  - The acceptance criteria limit of < 20.0 EU/device, in accordance with the standards specified in the "FDA Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers," issued in June 2012 (section III.11) for general medical devices (blood contacting and implanted), was successfully met.

Design Verification (Performance) Testing

- Product:
  - nsPVA particles visual inspection
    - Foreign particles inside the nsPVA syringe
    - Cleanliness and white color of nsPVA particles
  - nsPVA particles outside syringe
  - nsPVA particles moisture content
  - nsPVA particles hydration and suspension

- Packaging:
  - Compatibility of the syringe with contrast media
  - Visual inspections (syringe, pouch, carton and labels)
  - Pouch seal width
  - Pouch peel force
  - Pouch burst test
  - Pouch underwater bubble emission

The following standards were used for evaluation of packaging verification:

- ISO 11607-1 Second edition 2019-02 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems.*
- ISO 11607-2 Second edition 2019-02 *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes.*

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- ASTM F1140/F1140M-13 (Reapproved 2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- ASTM D4169-22 *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11 *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*
- ASTM F88/F88M-21 *Standard Test Method for Seal Strength of Flexible Barrier Materials*

Biocompatibility Testing:

There was no change to the Bearing nsPVA embolic particles. Therefore, biocompatibility testing was not repeated for the embolic particles. However, as the packaging of the embolic particles has changed from a glass vial to a polycarbonate syringe, biocompatibility testing was conducted specifically on the 20mL Polycarbonate Syringe of the Bearing nsPVA Express. The syringe is an external communicating device with a blood path that is indirect, and the contact duration is <24 hours. This testing was performed in accordance with the 2023 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." The biocompatibility testing results, provided in the table below, demonstrate that the Bearing nsPVA Express syringe is biocompatible.

Biological Endpoint	Test Method	Results
Cytotoxicity	ISO 10993-5	Non-Cytotoxic
Sensitization	ISO 10993-10	Non-Sensitizing
Intracutaneous Irritation	ISO 10993-10 ISO 10993-23	Non-irritating
Acute Systemic Toxicity	ISO 10993-11	Not acutely systemically toxic
Hemocompatibility	ISO 10993-4 ASTM F756-17	Non-hemolytic
Material Mediated Pyrogenicity	ISO 10993-11	Non-pyrogenic

Summary of Substantial Equivalence

Based on the non-clinical data, the subject device, Bearing nsPVA Express™, is as safe and effective as the predicate device Bearing nsPVA Embolization Particles. Therefore, the subject device is substantially equivalent to the predicate device.