September 23, 2025

Canyon Medical Inc.
Huiqi Jiang
RA Manager
Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue,
Jiangbei New Area
Nanjing, Jiangsu 210032
CHINA

Re: K250209
Trade/Device Name: Polyvinyl Alcohol Embolic Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: II
Product Code: KRD, NAJ
Dated: August 21, 2025
Received: August 22, 2025

Dear Huiqi Jiang:

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.

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,

Jason Roberts -S

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)*
K250209

Device Name
Polyvinyl Alcohol Embolic Microspheres

Indications for Use *(Describe)*
Polyvinyl Alcohol Embolic Microspheres are intended to be used for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors, including uterine fibroids.

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

Polyvinyl Alcohol Embolic Microspheres

1. 510(k) Owner

Canyon Medical Inc.

2. Submission Correspondent

Submitter Name: Canyon Medical Inc.

Address: Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, People's Republic of China

Official Correspondent: Ms. Huiqi Jiang

Position: RA Manager

E-mail: jhq@canyonmedical.com.cn

Telephone: +86-13241196637

3. Date of Preparation: August 22, 2025

4. Subject Device(s) Information

Common Name:	Polyvinyl Alcohol Embolic Microspheres
Trade Name:	Polyvinyl Alcohol Embolic Microspheres
Regulation Number:	21 CFR 870.3300
Classification Name:	Vascular embolization device
Device Class:	II
Product Code:	KRD, NAJ

5. Predicate Device(s) Information

Manufacturer:	Suzhou Hengrui Callisyn Biomedical Co., Ltd.
510(K) Number:	K173871
Trade Name:	CalliSpheres Embolic Microspheres, 8Spheres Embolic Microspheres
Regulation Number:	21 CFR 870.3300
Classification Name:	Vascular Embolization Device
Device Class:	II
Product Code:	KRD, NAJ

The predicate device has not been subject to a design related recall.

6. Device Description

The subject device polyvinyl alcohol embolic microspheres are compressible hydrogel microspheres with a regular shape, smooth surface, and calibrated size, which are formed as a result

of chemical modification on polyvinyl alcohol (PVA) materials. The embolic microspheres consist of a macromer derived from polyvinyl alcohol (PVA) and are hydrophilic, non-resorbable. The preservation solution is 0.9% sodium chloride solution.

The polyvinyl alcohol embolic microspheres available in dyed (blue) and clear (undyed with natural color). The subject device available in particle sizes from 75-1200μm and supplied sterile in sterile sealed glass vials which contain 1 mL, 2 mL, or 3 mL of microspheres suspended in 7mL, 7mL, or 6 mL of 0.9% sodium chloride solution, respectively. The subject device configurations are provided in Table 1 below.

Table 1. Device configuration

No.	Product Code	Dye Color	Calibrated Size (μm)	Size range (μm)	Quantity (embolic microspheres/0.9% sodium chloride solution)
1	PB-101	Blue	110	75~150	1mL/7mL
2	PB-102				2mL/7mL
3	PB-103				3mL/6mL
4	PB-201		200	100~300	1mL/7mL
5	PB-202				2mL/7mL
6	PB-203				3mL/6mL
7	PB-401		400	300~500	1mL/7mL
8	PB-402				2mL/7mL
9	PB-403				3mL/6mL
10	PB-601		600	500~700	1mL/7mL
11	PB-602				2mL/7mL
12	PB-603				3mL/6mL
13	PB-801		800	700~900	1mL/7mL
14	PB-802				2mL/7mL
15	PB-803				3mL/6mL
16	PB-1051		1050	900~1200	1mL/7mL
17	PB-1052				2mL/7mL
18	PB-1053				3mL/6mL
19	PW-101	Colorless	110	75~150	1mL/7mL
20	PW-102				2mL/7mL
21	PW-103				3mL/6mL
22	PW-201		200	100~300	1mL/7mL
23	PW-202				2mL/7mL
24	PW-203				3mL/6mL
25	PW-401		400	300~500	1mL/7mL
26	PW-402				2mL/7mL
27	PW-403				3mL/6mL
28	PW-601		600	500~700	1mL/7mL
29	PW-602				2mL/7mL

No.	Product Code	Dye Color	Calibrated Size (μm)	Size range (μm)	Quantity (embolic microspheres/0.9% sodium chloride solution)
30	PW-603				3mL/6mL
31	PW-801		800	700~900	1mL/7mL
32	PW-802				2mL/7mL
33	PW-803				3mL/6mL
34	PW-1051		1050	900~1200	1mL/7mL
35	PW-1052				2mL/7mL
36	PW-1053				3mL/6mL

Size (μm)	Indication – Hypervascular Tumors/ Arteriovenous Malformations	Indication-Uterine Fibroid
75~150	Yes	No
100~300	Yes	No
300~500	Yes	No
500~700	Yes	Yes
700~900	Yes	Yes
900~1200	Yes	Yes

7. Indications for Use

Polyvinyl Alcohol Embolic Microspheres are intended to be used for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors, including uterine fibroids.

8. Summary and Comparison of Technological Characteristics

Equivalence comparison has been identified with following summary of technical characteristics:

Table 2. Technological Characteristic Comparison Table

Device Characteristic	Subject Device: Polyvinyl Alcohol Embolic Microspheres	Predicate Device: CalliSpheres and 8Spheres Embolic Microspheres
510(k) Number	K250209	K173871
Classification	II	II
Product Code	KRD, NAJ	KRD, NAJ

Device Characteristic	**Subject Device: Polyvinyl Alcohol Embolic Microspheres**	**Predicate Device: CalliSpheres and 8Spheres Embolic Microspheres**
Regulation Number	21CFR 870.3300	21CFR 870.3300
Intended Use/ Indication for Use	Intended to be used for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors, including uterine fibroids.	Intended to be used for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors, including uterine fibroids.
Polymerization Method	Suspension polymerization	Suspension polymerization
Resorption	Non-resorbable	Non-resorbable
Appearance	Hydrogel microspheres with regular shape, smooth surface and calibrated size, Blue dyed or undyed	Hydrogel microspheres with regular shape, smooth surface and calibrated size. CalliSpheres: Blue dyed 8Spheres: Undyed
Microsphere Polymer Composition	Polyvinyl alcohol (PVA)	Polyvinyl alcohol (PVA)
Storage media	0.9% sodium chloride solution	0.9% sodium chloride solution
Size Range	Size range: 75-1200µm Labeled size range: 75-150µm 100-300µm 300-500µm 500-700µm 700-900µm 900-1200µm	Size range: 100-1200µm Labeled size range: 100-300µm 300-500µm 500-700µm 700-900µm 900-1200µm
Quantity (embolic microspheres/0.9% sodium chloride solution)	1mL/7mL 2mL/7mL 3mL/6mL	1mL/7mL 2mL/7mL
Packaging	Sealed in borosilicate glass vial	Sealed in borosilicate glass vial
Compressibility	50% by diameter	30% by diameter
Compatible Delivery Catheter	1.7-4.0Fr	1.7-4.0Fr
Radiopacity Method	Mixed with non-ionic contrast media prior to injection	Mixed with non-ionic contrast media prior to injection

Device Characteristic	Subject Device: Polyvinyl Alcohol Embolic Microspheres	Predicate Device: CalliSpheres and 8Spheres Embolic Microspheres
Delivery Method	Via catheter under fluoroscopic visualization	Via catheter under fluoroscopic visualization
Method of Supply	Sterile and single use	Sterile and single use
Sterilization	Moist heat and non-pyrogenic	Moist heat and non-pyrogenic
Shelf Life	Three years	Two years

The technological characteristics of the subject device are similar to those of predicate devices. The minimum particle size for the predicate device (100µm) is larger than the minimum particle size for the subject device (75µm). However, smaller sized microspheres have been cleared for similar indications, and has the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the following:

• Same indications for use
• Same fundamental technology

The differences in the particle sizes does not raise different questions of safety and effectiveness.

9. Non-Clinical Test Summary

The device is subject to Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices issued on 29 December 2004. The safety and effectiveness have been evaluated by non-clinical performance testing including:

Performance Testing

The following specifications and performance testing were evaluated on the subject device, and all tests were passed and demonstrated the subject devices can meet the product requirements.

- Appearance
- Quantity
- Microsphere Size
- Compressibility
- Catheter deliverability
- Suspension
- Water content per USP-NF 2025 <731> Loss on drying
- pH per USP-NF 2025 <791>
- Impurities and Residual Solvents
- Sterility per USP-NF 2025 <71>
- Bacterial Endotoxins per USP-NF 2025 <85>
- Packaging integrity
- Transportation
- Shelf life

Biocompatibility Evaluation

Biocompatibility testing for the subject device was conducted in accordance with FDA guidance,

Use of International Standard *ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*. Biocompatibility tests were completed, and the results demonstrate the subject device is biocompatible.

Table 3. Biocompatibility Evaluation Table

Biological Endpoint	**Test Method**	**Results**
MTT Cytotoxicity Test	ISO 10993-5:2009	Non-cytotoxic
ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10:2021	Non-sensitizer
ISO Intracutaneous Study in Rabbits	ISO 10993-10:2010	Non-irritant
ISO Acute Systemic Toxicity Study in Mice	ISO 10993-11:2017	No mortality or evidence of systemic toxicity
ASTM Hemolysis Study	ISO 10993-4:2017	Non-hemolytic
USP Rabbit Pyrogen Study, Material Mediated	ISO 10993-11:2021	Non-pyrogenic
ISO Muscle Implantation Study in Rabbits, 1 Week	ISO 10993-6:2016	The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article caused a minimal to no reaction as compared to the negative control article.
ISO Muscle Implantation Study in Rabbits, 4 Weeks	ISO 10993-6:2016	The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article caused a minimal to no reaction as compared to the negative control article.

ISO Muscle Implantation Study in Rabbits, 13 Weeks	ISO 10993-6:2016	The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article caused a minimal reaction as compared to the negative control article.

Chemical Characterization and Toxicological Risk Assessment

Chemical characterization testing was conducted on the subject device Polyvinyl Alcohol Embolic Microspheres in accordance with ISO 10993-18:2022. A Toxicological risk assessment in accordance with ISO 10993-17:2023, using a worst-case risk assessment approach was conducted based upon the findings of the exhaustive extraction. Using this approach, it was determined that the margins of safety (MOS) for potential chemical exposures indicated a low risk of chronic toxicity and carcinogenicity.

Sterility, Shipping, and Shelf -life

The proposed device is sterilized by moist heat steam which under validated parameters (121°C, 20 minutes) after sealing the vials to achieve a sterility assurance level (SAL) of 10^{-6} in accordance with USP <71> and ISO 17665:2015. Bacterial Endotoxin Levels were below the level of 0.5 EU/ml in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 3 year shelf-life.

- Package integrity test – after environmental conditioning, simulated transportation testing in accordance to ASTM D4169-22 on final, packaged, and sterile device.
- Sterile Barrier Packaging performed on the proposed device:
  - Dye penetration ASTM F1929-15
- Shelf-life of 3-years is validated using FDA recognized standard ASTM F1980 -21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Animal Study Testing

This animal study simulated the clinical use of polyvinyl alcohol embolization microspheres and performed partial renal artery embolization of healthy white swine through interventional surgery. The effectiveness evaluated by observing the performance of the intra-operative procedures, the parameters of the embolized vessel, and the embolization effect in the immediate and test periods. The safety and efficacy of the test article were initially evaluated by observing the overall recovery of the animals after the operation, and by combining hematological tests (blood coagulation and serum biochemistry, etc.), imaging changes in the kidneys, clinicopathology, gross anatomical observations, and histopathological manifestations of the embolized localities and the major organs of the whole body at multiple time points before and after the operation. The results demonstrate that the subject device is as safe and effective as the cleared Polyvinyl Alcohol Embolic

Microspheres (K173871).

10. Conclusion

The conclusions drawn from the comparison, analysis, and nonclinical testing above demonstrate that the proposed subject devices raise no new questions of safety or effectiveness, and are as safe, as effective, and perform as well as the legally marketed predicate devices for proposed indications for use.