7/31/2026

Suzhou Haowei Medical Technology Co., Ltd.
Jinyan Shi
RA Manager
Rm. 304, Bldg. 4, Tianyun Square, 111 Wusongjiang Ave.
Wuzhong District
Suzhou, Jiangsu 215124
China

Re: K252812
Trade/Device Name: UniPearls® Embolic Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Received: July 2, 2026

Dear Jinyan Shi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant 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.

Submission Number *(if known)*

K252812

Device Name

UniPearls® Embolic Microspheres

Indications for Use *(Describe)*

UniPearls® Embolic Microspheres are indicated for embolization of hypervascularized tumors including hepatoma, and peripheral arteriovenous malformations.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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) #: K252812

510(k) Summary

Prepared on: 2026-07-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Suzhou Haowei Medical Technology Co., Ltd.
Applicant Address	Room 304, Building 4, Tianyun Square, 111 Wusongjiang Avenue, Wuzhong District, Suzhou 215124, P.R.China Suzhou Jiangsu 215124 China
Applicant Contact Telephone	86 512-66387598
Applicant Contact	Ms. Jinyan Shi
Applicant Contact Email	shijinyan@hiwemed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	UniPearls® Embolic Microspheres
Common Name	Vascular embolization device
Classification Name	Device, Vascular, For Promoting Embolization
Regulation Number	870.3300
Product Code(s)	KRD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231554	UniPearls® Embolic Microspheres	KRD

Device Description Summary

21 CFR 807.92(a)(4)

UniPearls® Embolic Microspheres consist of non-biodegradable hydrogel microspheres packaged in a prefilled syringe. The prefilled syringe contains 1 mL of spheres suspended in 7 mL of physiological saline, 2 mL of spheres suspended in 6 mL of physiological saline, 3 mL of spheres suspended in 9 mL of physiological saline or 4 mL of spheres suspended in 12 mL of physiological saline. UniPearls® Embolic Microspheres are offered in seven sizes: 70µm, 100µm, 250µm, 400µm, 500µm, 700µm and 1000µm. The spheres are available in two colors: colorless and blue. The spheres are intended to be used with a delivery catheter with an inner diameter that is adequate for sphere delivery (not included). The finished product is sterilized by steam and is intended for single use only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

UniPearls® Embolic Microspheres are indicated for embolization of hypervascularized tumors including hepatoma, and peripheral arteriovenous malformations.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device are the same as those of the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics of the subject device are comparedto the predicate device, and the two devices are similar in

intendeuse, design, and principles of operation to the predicate device, Both devices are sterile, intended to be delivered with contrast througa catheter to promote targeted vessel embolization., The subject device and the predicate device difer in the following areas:
1.There is a diference in primary package between the two when they are delivered as sterile. The sterile package of the subject devichas been verified to be safe and effective.
2.The shelf life of the subiect device is longer than that of the predicate device, which is determined based on the accelerated aging test.
3.The volume is different, Two volume types are newly added for the subject device compared with the predicate device. The bench ter(volume test) has been conducted for the subject device, and all the results meet the specified product specification.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing, including: Appearance and Size Range, Catheter Deliverability, Compressibility Test, Water Content, Quantity Test, pH Test, Impurities and Residual Solvent, Bacterial Endotoxin, Sterility Test, Sample Size Calculation; animal study, etc.
The subject device design was evaluated through intended use, technical characteristics (including desian, material, chemicalcomposition, working principle, etc) between the subject device and the predicate device to provide evidence of safe and efective useof subject device. The test results met the specified acceptance criteria and did not raise new types of safety or effectiveness questionsThe subject device is substantially equivalent to the predicate device based on comparisons ofthe device functionality, technologicalcharacteristics,andindications for use.