



November 14, 2023

Suzhou Haowei Medical Technology Co., Ltd.
Jinyan Shi
RA Manager
Room 304, Building 4, Tianyun Square, No.111 Wusongjiang
Avenue, Guoxiang Street, Wuzhong District, Suzhou
Suzhou, Jiangsu 215124
CHINA

Re: K231554
Trade/Device Name: UniPearls® Embolic Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: II
Product Code: KRD
Received: October 10, 2023

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 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,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.

Division 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

Indications for Use

Submission Number (if known)

K231554

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.

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510(k) #: K231554

510(k) Summary

Prepared on: 2023-10-10

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Suzhou Haowei Medical Technology Co., Ltd.
Applicant Address	Room 304, Building 4, Tianyun Square, No.111 Wusongjiang Avenue, Guoxiang Street, Wuzhong District, Suzhou 215124, P.R.China Suzhou Jiangsu 215124 China
Applicant Contact Telephone	+86 0512-663875
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	KRD

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172372	QuadraSphere Microspheres	KRD

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

UniPearls® Embolic Microspheres consist of non-biodegradable hydrogel microspheres packaged in a 10 ml penicillin bottle. The penicillin bottle contains 1 ml of spheres suspended in 7 ml of physiological saline or 2 ml of spheres suspended in 6 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\(a\)\(6\)](#)

UniPearls® Embolic Microspheres are similar in intended use, design, and principles of operation to the predicate device. Both devices

are sterile, intended to be delivered with contrast through a catheter to promote targeted vessel embolization.

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 results of the testing demonstrated that the subject UniPearls® Embolic Microspheres met the pre-determined acceptance criteria applicable to the requirements and performance of the device.