May 30, 2024

Hangzhou Yangshun Medical Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, Shanghai 200120
CHINA

Re: K232934
Trade/Device Name: Sunsphere
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: II
Product Code: KRD, NAJ
Received: April 29, 2024

Dear Diana Hong:

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.

The 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)*
K232934

Device Name
Sunsphere

Indications for Use *(Describe)*
Sunsphere is intended to be used for the embolization of hypervascular tumors, including uterine fibroids, and arteriovenous malformations (AVMs).

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) Summary

Sunsphere

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K232934

1. Date of Preparation: May 30, 2024

2. Sponsor Identification

Sponsor Name**:** Hangzhou Yangshun Medical Technology Co. Ltd.
Address: Room 110, Building 2, No.357 Miaohouwang Road, Xixing Subdistrict, Binjiang District, Hangzhou, Zhejiang, China

Contact Person: Dong Hui
Position: Registration Director
Phone: +86-13716835300
Email: dongh@sunspheremedical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Phone: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sunsphere
Common Name: Polyvinyl Alcohol Embolic Microspheres

Regulatory Information
Regulation Name: Vascular Embolization Device
Regulation Number: 21 CFR 870.3300

Device Classification: Class II
Product Code: KRD (Device, Vascular, For Promoting Embolization), NAJ (Agents, Embolic, For Treatment Of Uterine Fibroids)

5. Identification of Predicate Device

Device Name: CalliSpheres Embolic Microspheres, 8Spheres Embolic Microspheres
510(k) Number: K173871
Manufacturer: Suzhou Hengrui Callisyn Biomedical Co., Ltd
Regulation Number 21 CFR 870.3300
Product Code: KRD, NAJ

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

6. Device Description

This proposed device is composed of polyvinyl alcohol embolic microspheres stored in a preservation solution of 0.9% sodium chloride. The proposed devices 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. Sunspheres are chemically cross-linked to form the microsphere. Microspheres are round in appearance with uniform size distribution and are available in blue dyed and undyed (colorless) microspheres.

The proposed device available in blue dyed and undyed (colorless) version, which are available in 1 mL and 2 mL volumes, and 6 different calibrated particle sizes from 90 to 1000 μm. Different particle sizes are distinguished by the color of the matching vial cap. The proposed device is supplied sterile and packaged in sealed glass vials. The device configurations of Sunspheres are described in Table 1 below.

Table 1. Product specification

Specification	Dye Color	Calibrated Size (μm)	Size Range (μm)	Quantity
F2B10090	Blue	90	70 -120	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B10200		200	150 – 250	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B10400		400	350 – 450	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B10600		600	550 – 650	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B10800		800	700 – 900	1 mL embolic microspheres/7 mL 0.9% sodium chloride

F2B11000		1,000	900 – 1100	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B20090		90	70 – 120	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B20200		200	150 – 250	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B20400		400	350 – 450	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B20600		600	550 – 650	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B20800		800	700 – 900	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2B21000		1,000	900 – 1100	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C10090	Colorless	90	70 – 120	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C10200		200	150 – 250	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C10400		400	350 – 450	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C10600		600	550 – 650	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C10800		800	700 – 900	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C11000		1,000	900 – 1100	1 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C20090		90	70 – 120	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C20200		200	150 – 250	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C20400		400	350 – 450	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C20600		600	550 – 650	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C20800		800	700 – 900	2 mL embolic microspheres/7 mL 0.9% sodium chloride
F2C21000		1,000	900 – 1100	2 mL embolic microspheres/7 mL 0.9% sodium chloride

7. Indications for Use:

Sunsphere is intended to be used for the embolization of hypervascular tumors, including uterine fibroids, and arteriovenous malformations (AVMs).

8. Technological Comparison to Predicate Device

Table 2. General Comparison

Item	**Proposed Device** K232934	**Predicate Device** K173871	**Remark**
Classification	II	II	Same
Product Code	KRD, NAJ	KRD, NAJ	Same
Regulation Number	21 CFR 870.3300	21 CFR 870.3300	Same
Indication for Use	The Sunsphere is indicated for use in the embolization of hypervascular tumors, including uterine fibroids, and arteriovenous malformations (AVMs).	CalliSpheres Embolic Microspheres and 8Spheres Embolic Microspheres are intended to be used for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors, including uterine fibroids.	Same
Polymerization Method	Suspension polymerization	Suspension polymerization	Same
Resorption	Non-resorbable	Non-resorbable	Same
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	Same
Microsphere Polymer Composition	Polyvinyl alcohol (PVA)	PVA	Same
Size Range (μm)	Size Range: 70 – 1,100μm Labeled size range: 70-120 150-250 350-450 550-650 700-900 900-1100	Size Range: 100 – 1,200μm Labeled size range: 100-300 300-500 500-700 700-900 900-1200	Different.
Size indicated for UAE (μm)	550-650 700-900 900-1100	500-700 700-900 900-1200	Different
Storage media	0.9% sodium chloride solution	0.9% sodium chloride solution	Same
Quantity of Microspheres	1 mL (in 7 mL 0.9% sodium chloride) 2 mL (in 7 mL 0.9% sodium chloride)	1 mL (in 7 mL 0.9% sodium chloride) 2 mL (in 7 mL 0.9% sodium chloride)	Same

Packaging	Device are sealed in borosilicate glass vial	Both CalliSpheres and 8Spheres are sealed in borosilicate glass vial	Same
Compressibility	30% by diameter	30% by diameter	Same
Delivery Method	Delivered to target position by Micro-Catheter under DSA.	Delivered to target position by Micro-catheter under DSA.	Same
Compatible Delivery Catheter	1.7-4.0Fr	1.7-4.0Fr	Same
Radiopacity Method	Mixed with non-ionic contrast agent prior to injection	Mixed with non-ionic contrast agent prior to injection	Same
Method of Supply	Sterile and single use	Sterile and single use	Same
Shelf Life	2 years	2 years	Same
Sterilization	Moist heat and non-pyrogenic	Moist heat and non-pyrogenic	Same

Both devices have the same intended use, and use the same embolization particle composition, vial sizes, and sterilization method. The minimum particle size for the proposed device (70 μm) is smaller than the minimum particle size for the predicate device (100 μm). The size ranges indicated for UAE for the proposed device are different from the predicate device size range for UAE. The proposed device range (550-1100 μm) is within the range listed for the predicate device (500-1200 μm). The differences in the particle sizes does not raise different questions of safety and effectiveness.

9. Non-Clinical Test Conclusion

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

Performance testing

The following specifications and performance testing were evaluated on the subject device:

- Appearance
- Microsphere Compressibility
- Microsphere Quantity in each Vial
- Microsphere Size
- Time in Suspension
- Catheter Deliverability
- Water Content per USP 39 NF 34 (2016) <731> Loss on drying
- pH per USP 39 NF 34 (2016) <791>
- Impurities and residual solvents per USP 39 NF 34 <1086>

Above, all tests were passed and demonstrated the proposed devices can meet the product requirements.

Biocompatibility testing

The biocompatibility evaluation for the proposed 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"*, issued September 8, 2023. The following tests were conducted for Sunsphere, for a permanent implant device in contact with blood:

Biological Endpoint	**Test Method**	**Results**
MTT Cytotoxicity Test	ISO 10993-5:2009	Non-cytotoxic
ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10:2010	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 ASTM F756:2017	Non-hemolytic
ASTM Partial Thromboplastin Time	ASTM F2382:2018	Non-activator
SC5b-9 Complement Activation Assay	ISO 10993-4:2017	Both the test article and the sponsor provided control were considered to be potential activators of the complement system. The test article was compared statistically to the control and the test article was lower than the control and was statistically different.
USP Rabbit Pyrogen Study, Material Mediated	ISO 10993-11:2017	Non-pyrogenic
Genotoxicity Mouse Lymphoma Assay	ISO 10993-3:2014	Non-mutagenic

Biological Endpoint	Test Method	Results
Bacterial Reverse Mutation Study	ISO 10993-3:2014	Non-mutagenic
ISO Systemic Toxicity Study in Rats Following Subcutaneous Implantation, 13 Weeks	ISO 10993-6:2016 ISO 10993-11:2017	There was no evidence of systemic toxicity from the test article following subcutaneous implantation in the rat. Microscopically, the test article was classified as causing minimal to no reaction.
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.
ISO Muscle Implantation Study in Rabbits, 26 weeks	ISO 10993-6:2016	The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article caused no reaction as compared to the negative control article.

Biological Endpoint	Test Method	Results
Chronic Systemic Toxicity and Carcinogenicity Evaluation	ISO 10993-18:2023	A chemical characterization study and toxicological risk assessment were used to support chronic systemic toxicity and carcinogenicity endpoints. The study was based on chemical characterization results and supported by information on the Sunsphere materials of construction, gathered toxicological data on these materials. A toxicological risk assessment was completed based on the results from the chemical characterization.

Chemical Characterization

Chemical characterization testing was conducted on Sunsphere in accordance with ISO 10993-18:2022. The testing consisted of exhaustive extraction of the microspheres in purified water, ethanol, and hexane. Extracts and normal saline were analyzed per Direct Injection Gas Chromatography Mass Spectrometry (DI-GCMS), Headspace Gas Chromatography Mass Spectrometry (HS-GC-MS), Liquid Chromatography High-Resolution Mass Spectrometry (LC-HRMS) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS) screening analysis.

Toxicological Risk Assessment

The toxicological risk assessment was performed to address the chronic systemic toxicity and carcinogenicity end point. For each detected compound, a toxicological risk assessment was conducted in accordance with ISO 10993-17: 2002 and ISO/TS 21726: 2019. The toxicological risk assessment was conducted on the detected compounds from the chemical characterization study. The amount of each detected compound is below the threshold of toxicological concern (TTC) value. The appropriate uncertainty factors are used to derive the tolerable intake (TI) limit as recommended in ISO 10993-17:2002. The results demonstrated that the margins of safety (MoS) for potential chemical exposures represented a low risk of chronic toxicity and carcinogenicity. The Sunsphere is not expected to raise an unacceptable toxicity risk to the exposed patients when used as intended.

Sterility, Shipping, and Shelf -life

The proposed device is sterilized by moist heat steam which under validated parameters (121℃, 30 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 2 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 2-years is validated using FDA recognized standard ASTM F1980 -21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Animal Performance Testing Conclusion

This study simulated the clinical use of Sunsphere and performed partial embolization of the right renal artery of healthy domestic pigs by interventional surgical procedures. The test article was Sunsphere, with particle size of 90 μm; the control article was the cleared predicate device 8Spheres (polyvinyl alcohol embolic microspheres - colorless), with particle size of 100 ~ 300 μm. The efficacy was evaluated by investigating the delivery performance, embolization effect immediate and within the study cycle. The safety of the test article in the study cycle was evaluated by investigating the postoperative animal recovery, clinical pathology, local embolization, gross anatomical observation, and systemic histopathological results at postoperative timepoints of 3, 8 and 28 days after embolization.

No clinically relevant intraoperative, postoperative, hematologic, coagulation, or major organ abnormalities other than the right kidney occurred. Among the serum biochemical parameters, the alanine aminotransferase (ALT) and aspartate aminotransferase (AST) in the test group and the control group were slightly increased in the short term after surgery, but there was no significant difference between the two groups and no physiological abnormality was reached. Histopathology results showed only a small microsphere shift and secondary tissue response in the upper pole of the right kidney on Day 8, but there was no significant difference between the test group and control group, and its severity and extent of involvement were very mild. Overall, the lower pole of the right kidney in the test group and control group presented similar gross lesions and histopathological features. Vascular changes and necrosis were observed to be equivalent in the test group on Day 8 and Day 29, consistent with the equivalent long term embolization performance results of test article. In conclusion, compared with the control article, the test article demonstrated efficacy and safety equivalent to the predicate in this animal study.

10. Conclusion

As described above, the subject devices have the same intended use as the predicate device. The differences in technological characteristics between the subject devices and the predicate do not raise different questions of safety and effectiveness. To evaluate the impact of the technological differences, performance testing was conducted as described above. The results of the testing demonstrate that the subject devices, Sunsphere, is

as safe and effective as the predicate device and supports a determination of substantial equivalence.