October 1, 2021

Suzhou Hengrui Hongyuan Medical Co., Ltd.
Qianqian Zhang
Regulatory Affairs Engineer
Building B9 Unit 201, No. 218 Xinghu Road, SIP
Suzhou, Jiangsu 215123
China

Re: K210562
Trade/Device Name: HRSpheres Narrow-Size Embolic Microspheres
Regulation Number: 21 CFR§ 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Code: KRD, NAJ
Dated: September 8, 2021
Received: September 16, 2021

Dear Qianqian Zhang:

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 (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 located 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.

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 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210562

Device Name
HRSpheres Narrow-Size Embolic Microspheres

Indications for Use *(Describe)*
HRSpheres Narrow-Size 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.

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510(k) Summary

HRSpheres Narrow-Size Embolic Microspheres
(per 21 CFR 807.92)

1. Submitter

Submitter Name:	Suzhou Hengrui Hongyuan Medical Co., Ltd
Address:	Building B9 Unit 201, No. 218 Xinghu Road, SIP, Suzhou, Jiangsu, China 215123
Phone:	+86-512-6835-6665
Contact Person:	Qianqian Zhang
Email:	zhangqianqian@hrmedical.com.cn
Date Prepared:	September 30, 2021

2. Subject Device

Device Name:	HRSpheres Narrow-Size Embolic Microspheres
Common or Usual Name:	Polyvinyl Alcohol Embolic Microspheres
Classification Name:	Vascular Embolization Device (21 CFR 870.3300)
Regulatory Class:	Class II
Product Code:	KRD (device, vascular, for promoting embolization), NAJ (agents, embolic, for treatment of uterine fibroids)

3. 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.

4. Device Description

HRSpheres Narrow-Size 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. HRSpheres Narrow-Size Embolic Microspheres consist of a macromer derived from PVA, and are hydrophilic, non-resorbable, and are available in a variety of diameters ranging from 70 – 1,200 μm. The preservation solution is 0.9% sodium chloride solution. The water content of a fully polymerized microsphere is 91% ~ 94%. Microspheres are compressible to enable smooth delivery through the indicated delivery catheter. The HRSpheres are available in dyed (blue) and clear (undyed with natural color). Blue-dyed microspheres aid in the visualization of the microspheres in the delivery syringe. HRSpheres Narrow-Size Embolic Microspheres are packaged in sterile sealed glass vials for single use only and available with 1 mL, 2 mL, or 3 mL microspheres volumes per vial.

HRSpheres Narrow-Size Embolic Microspheres can be delivered to a targeted area through typical microcatheters in the 1.7 – 4 Fr range. By blocking the blood supply to the target area, the tumor or malformation is starved of nutrients and shrinks in size. At the time of use, HRSpheres Narrow-Size Embolic Microspheres are mixed with a nonionic contrast agent to form a suspension solution and aid in visualization during a procedure. The device configurations are described in Table 1. Product codes beginning with "B" represent microspheres with blue dye (Reactive Blue #4) and codes beginning with "C" represent undyed microspheres. Among the various size ranges of HRSpheres Narrow-Size Embolic Microspheres, the sizes that can be used for uterine fibroid embolization are 500 μm, 700μm, 900 μm, 1200 μm.

Table 1: Device configurations of HRSpheres Embolic Microspheres

<table>
<tr><th rowspan="2">Product Code</th><th rowspan="2">Calibrated size (μm)</th><th rowspan="2">Size Range (μm)</th><th rowspan="2">Quantity</th><th colspan="2">Indication</th></tr>
<tr><th>Hypervascular Tumors / Arteriovenous Malformations</th><th>Uterine Fibroid</th></tr>
<tr><td>B107S007</td><td rowspan="3">70</td><td rowspan="3">70-100</td><td>1 mL microspheres: 7 mL 0.9% sodium chloride solution</td><td rowspan="3">Yes</td><td rowspan="3">No</td></tr>
<tr><td>B207S007</td><td>2 mL microspheres: 7 mL 0.9% sodium chloride solution</td></tr>
<tr><td>B306S007</td><td>3 mL microspheres: 6 mL 0.9% sodium chloride solution</td></tr>
<tr><td>B107S010</td><td>100</td><td>75-125</td><td>1 mL microspheres: 7 mL</td><td>Yes</td><td>No</td></tr>
</table>

Product Code	Calibrated size (µm)	Size Range (µm)	Quantity	Indication	
				Hypervascular Tumors / Arteriovenous Malformations	Uterine Fibroid
			0.9% sodium chloride solution		
B207S010			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
B306S007			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
B107S025	250	200-300	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	No
B207S025			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
B306S025			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
B107S040	400	350-450	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	No
B207S040			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
B306S040			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
B107S050	500	480-580	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
B207S050			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
B306S050			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
B107S070	700	650-750	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
B207S070			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
B306S070			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
B107S090	900	825-975	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
B207S090			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
B306S090			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
B107S120	1,200	1,000-1,200	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
B207S120			2 mL microspheres: 7 mL		

Product Code	Calibrated size (µm)	Size Range (µm)	Quantity	Indication	
				Hypervascular Tumors / Arteriovenous Malformations	Uterine Fibroid
			0.9% sodium chloride solution		
B306S120			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S007	70	70-100	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	No
C207S007			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S010			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S010	100	75-125	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	No
C207S010			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S010			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S025	250	200-300	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	No
C207S025			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S025			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S040	400	350-450	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	No
C207S040			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S040			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S050	500	480-580	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
C207S050			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S050			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S070	700	650-750	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
C207S070			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S070			3 mL microspheres: 6 mL		

Product Code	Calibrated size (µm)	Size Range (µm)	Quantity	Indication	
				Hypervascular Tumors / Arteriovenous Malformations	Uterine Fibroid
			0.9% sodium chloride solution		
C107S090	900	825-975	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
C207S090			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S090			3 mL microspheres: 6 mL 0.9% sodium chloride solution		
C107S120	1,200	1,000-1,200	1 mL microspheres: 7 mL 0.9% sodium chloride solution	Yes	Yes
C207S120			2 mL microspheres: 7 mL 0.9% sodium chloride solution		
C306S120			3 mL microspheres: 6 mL 0.9% sodium chloride solution		

5. Indications for Use

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

6. Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics of HRSpheres and the CalliSpheres and 8Spheres embolic beads is summarized in Table 2 below:

Table 2: Technological Characteristic Comparison Table

Performance Characteristics Comparison Table			
Device Characteristic	**Subject Device: HRSpheres Narrow-Size Embolic Microspheres**	**Predicate Device: CalliSpheres and 8Spheres Embolic Microspheres**	**Comment**
510(k) Number	K210562	K173871	N/A
Classification	II	II	Same
Product Code	KRD, NAJ	KRD, NAJ	Same

Performance Characteristics Comparison Table			
Device Characteristic	**Subject Device: HRSpheres Narrow-Size Embolic Microspheres**	**Predicate Device: CalliSpheres and 8Spheres Embolic Microspheres**	**Comment**
Regulation	21 CFR 870.3300	21 CFR 870.3300	Same
Indication for Use	HRSpheres Narrow-Size Embolic Microspheres are intended to be used for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors, including uterine fibroids.	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
Materials	Polyvinyl alcohol (PVA), N-acryloylaminoacetaldehyde dimethyl acetal, 2-acrylamido-2-methyl-1-propanesulfonic acid sodium salt, 0.9% sodium chloride solution, Reactive Blue Dye #4 (only for blue type microspheres)	Polyvinyl alcohol (PVA), N-acryloylaminoacetaldehyde dimethyl acetal (NAAADA), 2-acrylamido-2-methyl-1-propanesulfonic acid sodium salt, 0.9% sodium chloride solution, Reactive Blue Dye #4 (only for CalliSpheres)	Different. The differences in material do not raise different questions of safety and effectiveness.
Storage media	0.9% sodium chloride solution	0.9% sodium chloride solution	Same
Microsphere Diameter	Size range: 70-1,200µm Labeled size range: 70-100 µm 75-125 µm 200-300 µm 350-450 µm 480-580 µm 650-750 µm 825-975 µm 1,000-1,200 µm	Size range: 100-1,200µm Labeled size range: 100-300µm 300-500µm 500-700µm 700-900µm 900-1,200µm	Different. The subject device contains a smaller size range specification than the predicate device. The difference in size ranges does not raise different questions of safety and effectiveness.

Performance Characteristics Comparison Table			
Device Characteristic	**Subject Device: HRSpheres Narrow-Size Embolic Microspheres**	**Predicate Device: CalliSpheres and 8Spheres Embolic Microspheres**	**Comment**
Quantity of Microspheres (and storage media)	1 mL (in 7 mL saline), 2 mL (in 7 mL saline) or 3 mL (in 6 mL saline)	1 mL (in 7 mL saline) or 2 mL (in 7 mL saline)	Different. The difference in microsphere volumes does not raise different questions of safety and effectiveness.
Packaging	Sealed in borosilicate glass vial	Sealed in borosilicate glass vial	Same
Compressibility	50% by diameter	30% by diameter	Different. The subject device is able to tolerate a greater compressibility than the predicate device. The difference in compressibility tolerance does not raise different questions of safety and effectiveness.
Radiopacity Method	Mixed with non-ionic contrast media prior to injection	Mixed with non-ionic contrast media prior to injection	Same
Delivery Method	Via catheter under fluoroscopic visualization	Via catheter under fluoroscopic visualization	Same
Method of Supply	Sterile and single use	Sterile and single use	Same
Shelf Life	Three years	Two years	Different. The increased shelf life does raise different questions of safety and effectiveness.
Sterilization	Moist heat and non-pyrogenic	Moist heat and non-pyrogenic	Same

Overall, the differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

7. Summary of Non-clinical Performance Testing

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 HRSpheres Narrow-Size Embolic Microspheres have been evaluated by non-clinical performance testing including:

7.1 In-Vitro Bench Testing

The test items, methods, and method references of HRSpheres Narrow-Size Embolic Microspheres are as follows:

Table 3: Device Non-Clinical Performance Evaluations

Test Items	Test Methods	Results
Appearance	USP 39 - <1> Injections and Implanted Drug Products (Parenterals) –Product Quality Tests and <790> Visible Particulates In Injections	Met predefined acceptance criteria
Compressibility	Internal Methods	Met predefined acceptance criteria
Quantity	USP <1151> Pharmaceutical	Met predefined acceptance criteria
Size Range	Internal Methods	Met predefined acceptance criteria
Suspension	In House Methods	Met predefined acceptance criteria
Catheter Deliverability	In House Methods	Met predefined acceptance criteria
Water Content	USP 39 NF34 （2016）- <731> Loss on drying	Met predefined acceptance criteria
pH	USP 39 NF 34 (2016) - <791> pH	Met predefined acceptance criteria
Impurities and residual solvents	USP39 NF34 - <1086> Impurities in Drug Substances and Drug Products	Met predefined acceptance criteria
Sterility	USP <71> Sterility Tests	Met predefined acceptance criteria
Bacterial endotoxin	USP<85> Bacterial Endotoxins	Met predefined acceptance criteria

7.2 Packaging Integrity and Shelf Life

HRSpheres Narrow-Size Embolic Microspheres are supplied sterile and packaged in borosilicate glass vials.

According to ASTM F1980-16, accelerated aging tests equivalent to 3 years of shelf life were carried out on HRSpheres Narrow-Size Embolic Microspheres, with 3 batches of each tested for all device specifications. Accelerated aging tests for package integrity were also carried out on the packaging materials including the bottles, rubber closures, and aluminum plastic covers.

The results of the performance tests after accelerated aging demonstrated all samples met specifications. Therefore, the results support a 3 year shelf life of HRSpheres Narrow-Size Embolic Microspheres.

7.3 Sterilization and Shelf Life

HRSpheres Narrow-Size Embolic Microspheres are labeled as “Sterile” and “non-pyrogenic.” HRSpheres Narrow-Size Embolic Microspheres are sterilized by moist heat sterilization with validated parameters (121 ℃, 30 min) after sealing the vials. Sterilization validation was completed to a sterility assurance level (SAL) of 10^{-6} using the Overkill Approach per ANSI/AAMI/ISO 17665-1:2006(R)2013.

HRSpheres Narrow-Size Embolic Microspheres were tested for bacterial endotoxins per USP <85> Bacterial Endotoxins Test to a level of not more than 0.5 EU/mL in accordance with the requirements of FDA guidance document: Guidance for Industry: Pyrogen Endotoxins Testing: Questions and Answers, issued June 2012.

7.4 Chemical Characterization

Chemical characterization testing was conducted on HRSpheres Narrow-Size Embolic Microspheres. The testing consisted of exhaustive extraction of the microspheres in purified water, ethanol, and hexane. Extracts were analyzed per FTIR, GC-MS and UPLC-MS. Water extract was also analyzed by ICP-MS. A risk analysis 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.

7.5 Biocompatibility Evaluation

Biocompatibility testing was conducted in accordance with the 2020 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 following biocompatibility tests listed in Table 3 were completed, and the results demonstrate the subject device is biocompatible:

Table 4: Device Biological Endpoints

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
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.

Biological Endpoint	Test Method	Results
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 slight reaction as compared to the negative control article.
Chronic Systemic Toxicity and Carcinogenicity Evaluation	ISO 10993-1:2018 ISO 14971:2019 2020 FDA Biocompatibility Guidance	A biological risk assessment was used to support chronic systemic toxicity and carcinogenicity endpoints. The risk assessment was based on chemical characterization results and supported by information on the HRSpheres materials of construction, gathered toxicological data on these materials, and biological data on the HRSpheres.

8. Animal Study Testing

An animal study was performed on the healthy swine models to evaluate the safety and effectiveness of the HRSpheres Narrow-Size Embolic Microspheres. A total of 15 female domestic swine were selected for evaluation. The animal study was intended to simulate the clinical application of the embolization microspheres by interventional procedure for partial renal artery embolization. Seven pigs were selected for embolization with the test article (75 – 125 μm), and the other 8 pigs were selected for embolization with the control article (CalliSpheres Polyvinyl Alcohol Embolization Microspheres; K173871) (100 – 300 μm). Several preoperative and postoperative observation time points were selected, including 3, 8 and 29 days after embolization.

At each observation time point, the changes of hematology, blood coagulation and serum biochemistry, as well as the imaging changes and pathological changes of kidney were detected, and the performance differences of test article and control were compared. The safety and effectiveness of HRSpheres Narrow-size embolic

microspheres were comprehensively evaluated. These evaluations included the following:

1) Comparison of recanalization of the vessels/durability of occlusion of HRSpheres Narrow-size embolic microspheres and CalliSpheres Embolic Microspheres.

2) Comparison of local and systemic foreign body reactions of HRSpheres Narrow-size embolic microspheres and CalliSpheres Embolic Microspheres.

3) Comparison of the ease of delivery of HRSpheres Narrow-size embolic microspheres and CalliSpheres Embolic Microspheres.

4) Comparison of the rupture or puncture of the blood vessels of HRSpheres Narrow-size embolic microspheres and CalliSpheres Embolic Microspheres.

5) Comparison of the non-target embolization/device migration of HRSpheres Narrow-size embolic microspheres and CalliSpheres Embolic Microspheres.

6) Comparison of local and systemic foreign body reactions of HRSpheres Narrow-size embolic microspheres and CalliSpheres Embolic Microspheres.

Animal evaluation indexes of HRSpheres Narrow-Size Embolic Microspheres on day 3, 8, and 29 were comparable to those from the control group. Tissue reactions of both test and control groups were found to be mild and comparable. Preoperative and postoperative clinicopathological examination results demonstrated that there was no significant difference between test group and control group with respect to adverse reactions. The results demonstrate that the subject device is as safe and effective as the cleared CalliSphere Embolic Microspheres (K173871).

9. Conclusion

As described above, the subject device has the same intended use as the predicate device. The differences in technological characteristics between the subject device and the predicate device 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 device, HRSpheres, is as safe and effective as the predicate device. Therefore, HRSpheres are substantially equivalent to the predicate.