



Food and Drug Administration  
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Silver Spring, MD 20993-0002

December 21, 2015

Microvention, Inc.  
Naomi Gong  
Sr. Regulatory Affairs Project Manager  
1311 Valencia Ave  
Tustin, CA 92780

Re: K150870  
Trade/Device Name: HydroPearl Microspheres,  
Regulation Number: 21 CFR 870.3300  
Regulation Name: Vascular Embolization Device  
Regulatory Class: Class II  
Product Code: KR D, NAJ  
Dated: December 3, 2015  
Received: December 4, 2015

Dear Naomi Gong,

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. 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Herbert P. Lerner -S**

for Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150870

Device Name

HydroPearl Microspheres

Indications for Use (Describe)

The HydroPearl Microspheres are intended for embolization of arteriovenous malformations 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

**Trade Name:** HydroPearl™ Microspheres  
**Generic Name:** Vascular embolization device  
**Classification:** Class II, 21 CFR 870.330 (KRD/NAJ)  
**Submitted By:** MicroVention, Inc  
 1311 Valencia Avenue  
 Tustin, California U.S.A.  
**Contact:** Naomi Gong  
**Date:** March 30, 2015

**Predicate Devices:**

Number	Description	Clearance Date
K021397	Biosphere (Merit Medical) Embosphere Microspheres	November 22, 2002
K991549	Biosphere (Merit Medical) Embosphere Microspheres	April 26, 2000

**Device Description:**

The HydroPearl Microspheres are a pre-formed, compressible, precisely calibrated, spherical embolic agent consisting of a biocompatible hydrogel. The HydroPearl Microspheres are offered in a variety of diameters ranging from 75-1100 µm and are provided in a sterile syringe pre-filled with microspheres in phosphate buffered saline. The pre-filled syringe is packaged in a sealed sterile dispenser tray. The HydroPearl Microspheres are delivered to the treatment site through a delivery catheter.

**Indications For Use:**

The HydroPearl Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids.

**Technological Comparison:**

	Biosphere Medical Embosphere (K021397/K991549)	HydroPearl Microspheres
Indications for Use	Intended for embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids.	Same
Microsphere material	Acrylic polymer and impregnated with porcine derived gelatin	Polyethylene glycol diacrylamide
Microsphere diameter	40-1200 µm	75-1100 µm
Microsphere container	Contained in a sterile, 20 ml polycarbonate syringe	Same
Microsphere volume per syringe	1.0 or 2.0 mL Storage media: physiological saline	2.0 mL Storage media: phosphate buffered saline
Delivery method	Delivered to treatment site by catheter under fluoroscopic visualization	Same
Radiopacity method	Mixed with contrast media prior to injection	Same
Method of supply	Sterile and single use	Same
Sterilization Method	Steam	Same

## Verification and Test Summary:

Pre-clinical Testing		Result
Mechanical <ul style="list-style-type: none"> <li>• Compression</li> <li>• Robustness</li> <li>• Delivery force</li> <li>• Dimensional</li> <li>• Resilience</li> <li>• Time to suspension/time in suspension</li> </ul>	Microspheres are capable of: <ul style="list-style-type: none"> <li>• Temporary deformation with smooth passage through catheter</li> <li>• Syringe to syringe transfer</li> <li>• Delivery through catheter within force specification</li> <li>• Maintains diameter</li> <li>• Suspension (for reference)</li> </ul>	Pass
Chemical <ul style="list-style-type: none"> <li>• Residual solvents testing</li> <li>• pH test of solution</li> <li>• Syringe leachables testing</li> </ul>	<ul style="list-style-type: none"> <li>• Meets criteria for residuals</li> <li>• Maintains pH</li> <li>• Syringe does not leach into microsphere/PBS</li> </ul>	Meet
Magnetic resonance compatibility	Tested to be MR Safe	Pass
Catheter compatibility	Microspheres can be delivered through a catheter of 0.017” – 0.041” ID	Pass
Compatibility with contrast agents	Microspheres are compatible with contrast agent per IFU	Pass
Shelf Life (product/packaging)	After aging conditioning, the microspheres/packaging meet specifications	Pass
Animal testing – device compared to predicate device (1 day, 7 day, and 30 day)	To assess embolization effectiveness and histopathological evaluation (necrosis, inflammation, and off-target embolization)	Pass
Biocompatibility testing (ISO 10993-1) Cytotoxicity (ISO 10993-5) <ul style="list-style-type: none"> <li>- MEM elution assay</li> <li>- Agar diffusion assay</li> </ul> Sensitization/Irritation (ISO 10993-10) <ul style="list-style-type: none"> <li>- Guinea pig maximization sensitization</li> <li>- Intracutaneous reactivity</li> </ul> Hemocompatibility (ISO 10993-4) <ul style="list-style-type: none"> <li>- Hemolysis (Direct and Indirect)</li> <li>- Complement Activation</li> <li>- UPTT</li> </ul> Systemic toxicity (ISO 10993-11) <ul style="list-style-type: none"> <li>- Systemic toxicity</li> <li>- Rabbit pyrogen test</li> </ul> Implantation (ISO 10993-6) <ul style="list-style-type: none"> <li>- 2, 13, and 26 wk implantation</li> </ul> Genotoxicity (ISO 10993-3) <ul style="list-style-type: none"> <li>- Ames Test</li> <li>- Chromosomal aberration</li> <li>- Rodent Bone Marrow Micronucleus</li> </ul>	Subjected to full battery of biocompatibility testing	Pass
Packaging validation	Subjected to ISTA conditions – Packaging testing for adequacy	Pass
Sterilization validation	Meets criteria for ISO 17665-1	Pass

**Clinical Information:**

Other information provided in the 510(k) included published studies/literature on devices for uterine fibroid embolization.

**Conclusions:**

The data presented in this submission demonstrates that the HydroPearl Microspheres are as safe, as effective, and perform as well the predicate device, Biosphere (Merit Medical) Embosphere Microspheres.

In summary, the HydroPearl Microspheres described in this submission is substantially equivalent to the predicate device.