



Food and Drug Administration
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September 17, 2015

MicroVention, Inc.
Ms. Naomi Gong, RAC
Senior Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA, 92780

Re: K150958

Trade/Device Name: LifePearl Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: July 31, 2015
Received: August 03, 2015

Dear Ms. 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" (21CFR 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150958

Device Name

LifePearl Microspheres

Indications for Use (Describe)

LIFEPEARL™ Microspheres are indicated for embolization of hypervascular tumors and arteriovenous malformations (AVM's).

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 – K150958

Trade Name: LifePearl™ Microspheres
Generic Name: Vascular embolization device
Classification: Class II, 21 CFR 870.3300 (KRD)
Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California U.S.A.
714-247-8000
Contact: Naomi Gong
Date: April 8, 2015

Predicate Devices:

Number	Description	Clearance Date
K083091	Biocompatibles U.K. LC Bead/Bead Block Microspheres	December 24, 2008

Device Description:

The LifePearl Microspheres are a pre-formed, compressible, precisely calibrated, spherical embolic agent consisting of a biocompatible hydrogel. The LifePearl Microspheres are offered in a variety of diameters ranging from 100-400 µm and are provided in a polycarbonate syringe pre-filled with microspheres in phosphate buffered saline. The microspheres are dyed green to aid in visualization in the delivery syringe. The pre-filled syringe is packaged for single use and sterile in a sealed dispenser tray. The LifePearl Microspheres are delivered to the treatment site through a delivery catheter of internal diameter of ≥ 0.017 inch. At time of use, LifePearl is mixed with non-ionic contrast agent for visualization under fluoroscopy.

Indications For Use:

The LifePearl Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors.

Verification and Test Summary:

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

Technological Comparison:

	Biocompatibles UK LC Bead/Bead Block (K083091)	LifePearl Microspheres
Indications for Use	Intended for embolization of arteriovenous malformations and hypervascular tumors.	Same
Microsphere material	Macromer derived from polyvinyl alcohol (PVA)	Copolymer of Polyethylene glycol diacrylamide
Microsphere diameter	100-1200 µm	100-400 µm
Microsphere container	LC Beads: packaged in sealed glass vial Bead Block: packaged in polycarbonate syringe	Same as Bead Block
Microsphere volume per syringe	1.0 or 2.0 mL Storage media: phosphate buffered 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

Summary of Applicable Standards:

FDA Guidance on Vascular and Neurovascular Embolization Devices (2004)
 ISO 17665-1, Sterilization of healthcare products (Medical Device) – Moist Heat
 ISO 10993-1, Biological evaluation of medical devices

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the LifePearl Microspheres when compared with the predicate device, Biocompatibles LC Bead/Bead Block Microspheres.

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate similar basic design and construction,
- Are sterilized using same methods and processes.

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