January 22, 2020

MicroVention, Inc.
Ms. Analia Staubly
Sr. Project Manager, Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K192684
Trade/Device Name: HydroPearl Microspheres
Regulation Number: 21 CFR 876.5550
Regulation Name: Prostatic Artery Embolization Device
Regulatory Class: Class II
Product Code: NOY, KRD, NAJ,
Dated: September 25, 2019
Received: September 26, 2019

Dear Ms. Staubly:

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 801); 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,

for Angel Soler-Garcia, Ph.D.
Acting Assistant Director
Incontinence and Male Urological Devices Team (THT3B3)
DHT3B: Division of Reproductive, Gynecological, and Urological Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192684

Device Name
HYDROPEARL® Microspheres

Indications for Use *(Describe)*
The HydroPearl® Microspheres are intended for the embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids, and for embolization of prostatic arteries (PAE) for symptomatic benign prostatic hyperplasia (BPH).

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
COMMON NAME:	Embolization device
REGULATION NAMES:	Prostatic artery embolization device Vascular embolization device
CLASSIFICATION:	II, 21 CFR 876.5550 (NOY) II, 21 CFR 870.3300 (KRD/NAJ)
PRODUCT CODE:	NOY/KRD/NAJ
APPLICANT:	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656
ESTABLISHMENT REGISTRATION NUMBER:	3013556777
CONTACT:	Analia Staubly Sr. Project Manager, Regulatory Affairs analia.staubly@microvention.com
DATE SUMMARY PREPARED:	September 25, 2019
PREDICATE DEVICE:	BioSphere Medical S.A. Embosphere Microspheres (DEN160040)
REFERENCE DEVICE:	HydroPearl™ Microspheres (K150870)
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 75-1100µm 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 the embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids, and for embolization of prostatic arteries (PAE) for symptomatic benign prostatic hyperplasia (BPH).

TECHNOLOGICAL CHARACTERISTICS AND PRODUCT FEATURE COMPARISON:

Characteristics	Predicate Device: Embosphere Microspheres (DEN160040)	Reference Device: HydroPearl Microspheres (K150870)	Subject Device: HydroPearl Microspheres
Intended Use	Indicated for use in embolization of arteriovenous malformations, hypervascular tumors, including symptomatic uterine fibroids and prostatic arteries for symptomatic benign prostatic hyperplasia (BPH).	Intended for the embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids.	Same as Predicate Device
TECHNICAL			
Microsphere Material	Acrylic polymer impregnated with porcine delivered gelatin.	Polyethylene glycol diacrylamide and glycerol monomethacrylate	Same as Reference Device
Microsphere Diameter	Size Range: 40 – 1200 µm Labeled size range: 40 - 120 µm 100 - 300 µm 300 - 500 µm 500 - 700 µm 700 - 900 µm 900 - 1200 µm	Size Range: 75 – 1100 µm Labeled size: 75 µm 200 µm 400 µm 600 µm 800 µm 1100 µm	Same as Reference Device
Microsphere Container	Contained in a sterile, 20 ml polycarbonate syringe.	Same as Predicate Device	Same as Predicate Device
Microsphere volume per syringe	1.0 or 2.0 ml, in physiological saline.	2.0 ml in phosphate buffered saline (PBS)	Same as Reference Device
Radiopacity Method	Mixed with contrast media prior to injection.	Same as Predicate Device	Same as Predicate Device
Delivery Method	Via catheter under radiographic imaging.	Same as Predicate Device	Same as Predicate Device
STERILIZATION AND PACKAGING			
Sterilization Method.	Steam sterilization.	Same as Predicate Device	Same as Predicate Device
Packaging	Pre-filled syringe, placed in a polycarbonate tray and sealed with a peel away Tyvek lid, placed inside bleached sulfate carton box.	Same as Predicate Device	Same as Predicate Device
Method of Supply	Sterile and single use.	Same as Predicate Device	Same as Predicate Device

VERIFICATION AND TEST SUMMARY:

Non-clinical testing was performed on the HydroPearl Microspheres, reference device, to provide reasonable assurance that the proposed device has been designed and tested to assure conformance to special requirements for its intended use. A risk assessment has been performed and demonstrates that the expanded indication did not require additional bench, biocompatibility, packaging or sterilization. All existing testing in the previous HydroPearl Microsphere pre-market submission remains applicable.

Comparative mechanical testing was conducted to compare the performance of the HydroPearl Microspheres to that of legally marketed devices for the same indication. The HydroPearl Microspheres performed equivalently to the Embosphere Microspheres, predicate device, in comparative mechanical testing. Pre-clinical animal testing was also performed in animal models representing the renal and prostatic vasculature. The HydroPearl performed similarly to the Embosphere Microspheres and had favorable embolization results in both studies.

CLINICAL INFORMATION:

Existing real-world data from a single, US center was analyzed retrospectively for the purpose of expanding the existing indication for the HydroPearl Microspheres to include embolization of prostatic artery embolization (PAE) for symptomatic benign prostatic hyperplasia (BPH). The retrospective analysis consisted of 17 patients that underwent prostatic artery embolization (PAE) using HydroPearl Microspheres for the treatment of symptomatic benign prostatic hyperplasia (BPH). The primary objective was to collect data of the procedure safety and efficacy, which included age, prostate volume baseline, baseline International Prostate Symptom Score + Quality of Life score (IPSS+QoL), unilateral vs bilateral embolization, size of particles used, complications and follow-up IPSS+QoL. The primary endpoint was reduction in IPSS score during the follow-up period.

Demographics and Baseline Characteristics:

Twenty-three patients were identified. 17 patients returned consent forms and their data was included in this study.

The mean age of the patients included was 70 (range; 55-85) and their mean prostate volume was 63 ml (range; 27-140). One of the patients relied on clean intermittent catheterization (CIC) for voiding and the rest were able to void without a catheter. Fourteen of seventeen patients were on BPH medications at the time of PAE.

All 17 patients underwent bilateral prostatic artery embolization. Embolization was performed with either 75 µm HydroPearl (n=2), 200 µm HydroPearl (n=3) or 75 µm followed by 200 µm HydroPearl (n=12).

Primary Endpoint Results:

Mean follow up period was 8.6 months (range; 1-12). Mean baseline International Prostate Symptom Score was 20.7 (range; 4-30) at baseline and 9.1 (range; 2-18) at latest follow-up ($p<0.05$). Mean Quality of Life Score was 3.7 (range; 1-6) at baseline and 1.2 (range; 0-3) at follow-up ($p<0.05$). The single patient who relied on CIC for voiding catheterized 5 times a day before PAE and 0 or 1 time a day after PAE. Seven of the 14 patients on BPH medications at

baseline no longer took these medications at their latest follow-up and two additional patients were able to reduce their daily medications.

Technical and Clinical Success Results:

Technical success, defined as bilateral prostate artery embolization, was achieved in all 17 patients. Clinical success was achieved in 16/17 patients (94%). The single patient that was considered a clinical failure underwent PAE with the goal of no longer requiring BPH medication after the procedure because of the side-effects that he experienced. His LUTS were well controlled on the medication prior to PAE (IPSS of 4). Post-PAE, he was able to cease taking medication, but his symptoms did mildly worsen (IPSS of 10).

Safety Results:

One major complication was reported that involved hospitalization of one subject 2 days after PAE to treat acute prostatitis. The patient was discharged after a 4-day admission without any residual effects. Additional minor complications that were reported included hematuria (n=1) and hematospermia (n=1). These two adverse events were likely the result of mild non-target embolization and are expected complications of PAE.

Study Conclusion:

PAE performed with HydroPearl Microspheres resulted in clinical success in nearly all the patients included in this analysis. The single exception was a patient who already had his LUTS well controlled on alpha-blocker medication, but who desired to no longer take this medication, which was accomplished after PAE. Additionally, half of the patients who presented at baseline on BPH medication, no longer required them after PAE.

In addition to the retrospective analysis, MicroVention Inc. conducted a comprehensive review of relevant clinical literature to assess whether any issues of safety or effectiveness were raised using microparticle embolic devices for prostatic artery embolization (PAE) for symptomatic benign hyperplasia (BPH). The literature review concludes that PAE is a safe, minimally invasive, and efficacious procedure with low rate of adverse events, particularly those related to the embolic agent.

CONCLUSION:

Based on the indications for use, technological characteristics, safety and performance testing, and clinical evidence, the HydroPearl Microspheres have been shown to support safe effective use in humans for prostatic artery embolization for symptomatic benign hyperplasia (BPH) and are substantially equivalent to Embosphere Microspheres

The HydroPearl Microspheres demonstrates compliance with the Special Controls under 21 CFR 876.5550 for the expanded indication for use and 21 CFR 870.3300.