April 20, 2021

Biocompatibles UK Ltd (part of Boston Scientific Corporation)
% Christina Fischer
Principal Regulatory Affairs Specialist
Boston Scientific Medizintechnik GmbH
Daniel-Goldbach-Straße 17 - 27
Ratingen, 40880
GERMANY

Re: K203276
Trade/Device Name: Bead Block (100 - 300µm, 1ml), Bead Block (300 - 500µm, 1ml), Bead Block (500 - 700µm, 1ml), Bead Block (700 - 900µm, 1ml), Bead Block (900 - 1200µm, 1ml), Bead Block (100 - 300µm, 2ml), Bead Block (300 - 500µm, 2ml), Bead Block (500 - 700µm, 2ml), Bead Block (700 - 900µm, 2ml), Bead Block (900 - 1200µm, 2ml)
Regulation Number: 21 CFR 876.5550
Regulation Name: Prostatic Artery Embolization Device
Regulatory Class: II
Product Code: NOY
Dated: March 3, 2021
Received: March 4, 2021

Dear Christina Fischer:

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 Mark Antonino, M.S.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K203276

Device Name

Bead Block (100 - 300µm, 1 ml) (EB1S103);
Bead Block (300 - 500µm, 1 ml) (EB1S305);
Bead Block (500 - 700µm, 1 ml) (EB1S507);
Bead Block (700 - 900µm, 1 ml) (EB1S709);
Bead Block (900 - 1200µm, 1 ml) (EB1S912);
Bead Block (100 - 300µm, 2 ml) (EB2S103);
Bead Block (300 - 500µm, 2 ml) (EB2S305);
Bead Block (500 - 700µm, 2 ml) (EB2S507);
Bead Block (700 - 900µm, 2 ml) (EB2S709);
Bead Block (900 - 1200µm, 2 ml) (EB2S912)

Indications for Use *(Describe)*

Bead Block microspheres are intended to be used for the embolization of hypervascular tumours, including uterine fibroids (UFE) and arteriovenous malformations (AVMs). Bead Block microspheres are also intended 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.

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

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biocompatibles UK Ltd (part of Boston Scientific Corporation)
Applicant Address	Chapman House, Weydon Lane Surrey Farnham GU9 8QL United Kingdom of Great Britain and Northern Ireland
Applicant Contact Telephone	+491621788391
Applicant Contact	Mrs. Christina Fischer
Applicant Contact Email	christina.fischer@bsci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Bead Block (100 - 300µm, 1 ml) (EB1S103); Bead Block (300 - 500µm, 1 ml) (EB1S305); Bead Block (500 - 700µm, 1 ml) (EB1S507); Bead Block (700 - 900µm, 1 ml) (EB1S709); Bead Block (900 - 1200µm, 1 ml) (EB1S912); Bead Block (100 - 300µm, 2 ml) (EB2S103); Bead Block (300 - 500µm, 2 ml) (EB2S305); Bead Block (500 - 700µm, 2 ml) (EB2S507); Bead Block (700 - 900µm, 2 ml) (EB2S709); Bead Block (900 - 1200µm, 2 ml) (EB2S912)
Common Name	Prostatic artery embolization device
Classification Name	Agents, Embolic, For Treatment Of Benign Prostatic Hyperplasia
Regulation Number	876.5550
Product Code	NOY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
DEN160040	Embosphere Microspheres	NOY
K150876	Bead Block	KRD

Device Description Summary

21 CFR 807.92(a)(4)

Bead Block, a permanent intravascular implant, is made up of preformed soft, compressible, biocompatible, hydrophilic, non-resorbable and precisely calibrated microspheres that occlude vessels for the purpose of blocking the blood flow to a target tissue. Bead Block compressible microspheres consist of a macromer derived from polyvinyl alcohol (PVA). The fully polymerized microsphere is approximately 90-95% water and is compressible to approximately 30% by diameter. Bead Block microspheres are dyed blue to aid in the visualization of the microspheres in the delivery syringe. The microspheres can be suspended in contrast agents and delivered through microcatheters to the target location.

Bead Block is available in bead sizes from 100 – 1200µm and supplied sterile in 20ml syringes which contain 1 or 2 ml of beads suspended in 6 or 5 ml of phosphate buffered saline, respectively. The different bead sizes of the product are differentiated by differently colored labels and syringe end caps.

Bead Block is provided as a single use, non-pyrogenic, sterile (steam sterilized) device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Bead Block microspheres are intended to be used for the embolization of hypervascular tumours, including uterine fibroids (UFE) and arteriovenous malformations (AVMs). Bead Block microspheres are also intended for embolization of prostatic arteries (PAE) for symptomatic benign prostatic hyperplasia (BPH).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device Bead Block and the predicate device Embosphere Microspheres have the same intended use and indications for use. They are both intended for the embolization of hypervascular tumors, including uterine fibroids and arteriovenous malformations and for prostatic artery embolization for benign prostate hyperplasia. The subject device Bead Block has the same intended use (embolization of vessels) compared to the reference device, Bead Block (K150876) with an extension of the indication for use to include prostatic artery embolization.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device Bead Block and the predicate device Embosphere Microspheres are size calibrated spherical microspheres delivered by microcatheters to occlude a target blood vessel. They have similar technological characteristics including the following:
- Size calibrated microspheres for embolization in similar size ranges (Bead Block 100 – 1200µm, Embosphere 40 – 1200µm). The Bead Block size intended to be used for PAE (100 – 300µm, 300 – 500µm) are identically available for the primary predicate device
- Steam sterilized, single use device
- Biocompatible, non-resorbable polymer
- Delivery via microcatheter to the site of desired embolization
- Visualization of the embolization process using radiographic imaging

Bead Block and the predicate device have minor different technological characteristics, as the subject device is made of polyvinyl alcohol and the predicate device is made of acrylic polymer and porcine derived gelatin. However, the difference in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.
The Bead Block microspheres (subject device) are identical to the reference device, Biocompatible's Bead Block (K150876) in design / technological characteristics, manufacturing, function, material, packaging, sterilization method and principle of operation. MR safety is added to the labeling for Bead Block based on a scientific rational referring to the non-ferrous composition of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The determination of substantial equivalence, for the extension of the Indication for Use to include prostatic artery embolization, did not require non-clinical performance testing. Existing performance testing, which includes bench testing, biocompatibility testing and animal studies, submitted in previous premarket submissions remain valid for Bead Block microspheres.

Previous bench testing of Bead Block included determination of residuals (starting material, solvents), visual inspection (visual defects, color, solution clarity), catheter delivery, including catheter clogging, formation of aggregates, ease of injection, and shape of embolization particle after injection, confirmation of size range, particle fiber shedding, pH, packaging integrity, shelf life, sterility and endotoxins.

Previous biocompatibility testing for Bead Block included genotoxicity, hemolysis, cytotoxicity, implantation, sensitization, intracutaneous reactivity as well as acute, subchronic and chronic toxicity testing. The studies have shown that the Bead Block material is biocompatible for its intended use.

Six animal studies were previously performed for Bead Block to demonstrate the safety and effectiveness of Bead Block in its intended use as an embolic agent. These studies were conducted employing a swine arteriovenous malformation model, rabbit, swine, and sheep renal and uterus embolization models, and a penetration model in sheep uterus. Comparison to the predicate device Embosphere was studied in the swine model and similar behavior of the embolic devices was shown.

Bead Block is MR Safe, based on scientific rationale as per the requirements in the Guidance for Industry and Food and Drug Administration Staff Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) environment (Dec 2014). Bead Block's materials are non-ferrous therefore supporting the conclusion of MR Safe in the MR environment.

A retrospective data review was designed to collect data on the effects of Bead Block on safety as well as effectiveness. The data review assessed International Prostate Symptom Score (IPSS), erectile function (IIEF), Quality of Life (QoL), Prostate volume (PV) and objective measures of urinary flow in male patients with moderate to severe lower urinary tract symptoms (LUTS) due to BPH who underwent PAE procedure.
Overall, 232 patients were included in this study. Bead Block 100-300 µm was used in 3 patients (1%), 300-500 µm in 220 patients (95%) and unknown bead size in 9 patients (4%).

Baseline Characteristics (no of patients)
Age (years) 65.2 ± 8.2 (226)
IPSS 21.8 ± 7.0 (167)
Quality of Life (QoL) 4.3 ± 1.0 (168)
Prostate Volume (ml) 86.4 ± 47.4 (180)
Qmax (peak urinary flow) (ml/s) 10.4 ± 6.5 (154)
PVR (Post-void residual volume) (ml) 105.2 ± 116.7 (154)

The results show that at 12 months post-embolization, 85% of patients treated with Bead Block reported a decrease in their total IPSS by at least 3 points, and 62% patients dropped at least 1 symptom category, from severe to moderate or moderate to mild. Statistically significant and clinically relevant improvement in total IPSS, QoL, PSA and prostate volume at 12 months ($p<0.001$) has been observed. Maximum urine flow (Qmax) and post-void residual (PVR) also showed improvement tendency at 12 months ($p = 0.059$ and 0.1). PAE using Bead Block did not impair sexual function as measured by IIEF.

Observed adverse events (AEs) were generally non-serious and transient. Overall, 149/232 patients (64.2%) reported at least one AE over the course of the study, most commonly renal and urinary disorders which were reported by 128 patients (55.2%). Dysuria (reported by 96/232 patients (41.4%)) and pollakiuria (reported by 105/232 patients (45.3%)) were the most common AEs.

Based on the technological characteristics and intended use along with the non-clinical and clinical data for Bead Block provided or referenced in this submission, it has been demonstrated that Bead Block used for the embolization of the prostatic artery for treatment of benign prostatic hyperplasia is an effective and well tolerated treatment in the study population, with comparable outcomes to Embosphere Microspheres. Bead Block is considered substantially equivalent to the predicate Embosphere Microspheres in safety and effectiveness for the embolization of the prostatic artery for treatment of benign prostatic hyperplasia.
Bead Block demonstrates compliance with the Special Controls under 21 CFR876.5550 for the expanded indication for use to include prostatic artery embolization. In addition, Bead Block is demonstrated to be MR safe based on its material characteristics in alignment with the requirements of the Guidance Document Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment. The expansion of the indication for use and the addition of MR compatibility information to the labeling do not raise new questions of safety or effectiveness.