May 4, 2021

Zimmer Biomet Spine Inc.
% Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K203218
Trade/Device Name: CaP Spheres Pellet Pack™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: October 29, 2020
Received: November 2, 2020

Dear Ms. Scifert:

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,

Pooja Panigrahi -S

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic 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.

510(k) Number *(if known)*
K203218

Device Name
CaP Spheres Pellet Pack™

Indications for Use *(Describe)*
CaP Spheres Pellet Pack™ is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. CaP Spheres Pellet Pack™ is intended to be used in conjunction with autograft bone as a bone graft extender and gently packed into bony voids or gaps in the posterolateral spine. CaP Spheres Pellet Pack™ provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

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
CaP Spheres Pellet Pack™ Bone Void Filler
25 March 2021

Company: Zimmer Biomet Spine
10225 Westmoor Drive
Westminster, CO 80021
1-800-447-3625

Company Contact: Ted Kuhn – Director, Regulatory Affairs

Official Correspondent: Christine Scifert – MRC Global, LLC

Trade Name: CaP Spheres Pellet Pack™

Common Name: Filler, Bone Void, Calcium Compound

Classification: Class II

Regulation Number: 21 CFR 888.3045 (Resorbable calcium salt bone void filler device)

Panel: Orthopedic

Product Code: MQV

Device Description:
CaP Spheres Pellet Pack™ is a synthetic, osteoconductive, and resorbable bone void filler device consisting of hollow and microporous biphasic calcium phosphate spheres contained within a resorbable mesh pouch to aid in intraoperative handling. The device may be implanted directly, or hydrated with saline or autologous blood, and is intended to be combined with autograft.

Indications for Use:
CaP Spheres Pellet Pack™ is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. CaP Spheres Pellet Pack™ is intended to be used in conjunction with autograft bone as a bone graft extender and gently packed into bony voids or gaps in the posterolateral spine. CaP Spheres Pellet Pack™ provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

Substantial Equivalence:
The subject components are substantially equivalent to the following predicate devices:

Primary Predicate:

AttraX Putty, Progentix Orthobiology B.V. (K151584)

Secondary Predicates:

MAGNIFUSE® Bone Graft, Medtronic Sofamor Danek USA (K123691)
Vitoss Bioactive Foam Bone Graft Substitute, Orthovita, Inc. (K083033)

The subject components are similar in indications, physical and chemical specifications, technological characteristics, and materials to the primary predicate AttraX Putty. The PGA mesh bag encasing the CaP spheres is similar to that of the secondary predicate MAGNIFUSE®. The size range offered as well as the degradation profile of both the CaP Spheres Pellet Pack™ and MAGNIFUSE® are similar. Therefore, it can be concluded that the subject CaP Spheres does not raise new questions of safety and effectiveness when compared to the predicate devices.

Performance Testing:

The subject CaP Sphere Pellet Pack™ has undergone a Biological Safety Risk Assessment based on ISO 10993-1, Biological Evaluation of Medical Devices and 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", as recommended in the "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA". Results of bench testing and animal data presented no evidence of an unwanted biological response.

The subject CaP Sphere Pellet Pack™ also underwent the following performance bench testing to determine the physical and chemical composition of the CaP Spheres: XRay Diffraction (XRD), Fourier Transform Infrared (FTIR) Spectrometry, Porosity (Mercury Porosimetry), surface area analysis (Brunauer-Emmett-Teller, BET), Heavy Metal elemental analysis, Trace element analysis, and degradation testing. Additional performance bench testing was performed on the PGA mesh which encases the spheres. This testing included Fourier Transform Infrared (FTIR) Spectrometry, Size Exclusion Chromatography, Differential Scanning Calorimetry (DSC), and degradation testing. All testing yielded acceptable results.

A sterilization validation was performed in accordance with *ISO 11137, Sterilization of Health Care Products – Radiation* to ensure a sterility assurance level (SAL) of 10^{-6}. Shelf life testing was performed to verify maintenance of a sterile barrier as well as product performance characteristics after aging. Pyrogenicity (LAL) testing was performed on the final device. All testing yielded acceptable results.

Finally, an in vivo evaluation of the subject CaP Spheres Pellet Pack™ combined with autograft was performed in a clinically relevant, single-level posterolateral spinal fusion animal model. The study demonstrated that the test group when used as an autograft extender, CaP Spheres can safely support spine fusion in equivalence to predicate AttraX Putty with autograft which was used as an extender.

Conclusion:

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.