October 19, 2019

Baxter Healthcare Corporation
Phillip Romei
Specialist, Global Regulatory Affairs
32650 N. Wilson Road
Round Lake, Illinois 60073

Re: K191513
Trade/Device Name: Altapore Shape
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 16, 2019
Received: September 18, 2019

Dear Mr. Romei:

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,

Laurence D. Coyne, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191513

Device Name
Altapore Shape

Indications for Use *(Describe)*
ALTAPORE SHAPE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine).
ALTAPORE SHAPE must be used in combination with autograft as a bone graft extender in posterolateral spinal fusion procedures. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ALTAPORE resorbs and is replaced with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5. 510(k) Summary

October 17, 2019

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Bone Void Filler
Trade/Device Name: ALTAPORE SHAPE
Classification Panel: 87 Orthopedic
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV

Table 1. Model Numbers for ALTAPORE

Model Number	Name
1508043	ALTAPORE SHAPE, 1.6 ml small cylinder
1508044	ALTAPORE SHAPE, 2.6 ml medium cylinder
1508045	ALTAPORE SHAPE, 8 ml large cylinder
1508046	ALTAPORE SHAPE, 15.8 ml large strip

PREDICATE AND REFERENCE DEVICES:

ALTAPORE SHAPE is substantially equivalent to the following predicate and reference devices (Table 2):

Table 2. Predicate and Reference Devices

Device	Company	510(k)	Clearance Date
ALTAPORE (Predicate Device)	Baxter Healthcare Corporation	K181225	August 31, 2018
ACTIFUSE SHAPE (Reference Device)	Baxter Healthcare Corporation	K082575	November 25, 2018
MASTERGRAFT® Putty (Predicate Device)	Medtronic Sofamor Danek USA, Inc.	K140375	April 18, 2014

DESCRIPTION OF THE DEVICE:

ALTAPORE SHAPE is a bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler. The interconnected and open porous structure of the silicate-substituted calcium phosphate phase of ALTAPORE SHAPE is similar to human cancellous bone and is intended to support bone growth with macro and micro-porosity. The microgranule phase ALTAPORE SHAPE is composed solely of elements that exist naturally in normal bone (Ca, P, O**,** H, Si).

ALTAPORE SHAPE is supplied as a shaped wax-like putty in a sterile pouch containing ALTAPORE microgranules, sized 1-2 mm, 80-85% total porosity, suspended in an absorbable Alkylene Oxide co-polymer carrier. ALTAPORE does not set in-situ following implantation. ALTAPORE is available as a 1.6 ml small cylinder, 2.6 ml medium cylinder, 8 ml large cylinder, and 15.8 ml large strip.

ALTAPORE SHAPE is designed for use as a standalone bone graft substitute or as an autograft extender. While not necessary, the product can be mixed with autologous blood or autologous bone at the discretion of the surgeon.

ALTAPORE SHAPE is bioactive based on *in vitro* studies that show it forms a surface apatite-layer when submerged in simulated body fluid that contains the same ion concentrations as human blood plasma. This apatite layer provides scaffolding onto which the patient's new bone will grow, allowing complete repair of the defect.

ALTAPORE SHAPE is osteoconductive based on *in vivo* animal studies that show it achieves bone healing in a critical defect model as confirmed with radiographic,

histolopathological, histomorphometric, and mechanical analyses. ALTAPORE SHAPE undergoes cell-mediated remodeling and is replaced by natural bone.

INDICATIONS FOR USE

ALTAPORE SHAPE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine).

ALTAPORE SHAPE must be used in combination with autograft as a bone graft extender in posterolateral spinal fusion procedures. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ALTAPORE resorbs and is replaced with bone during the healing process.

PURPOSE OF SUBMISSION

The purpose of this submission is to introduce the ALTAPORE SHAPE bone void filler to the market. The proposed device is a suspension of ALTAPORE microgranules currently used in Baxter's ALTAPORE Bone Graft substitute product lines, previously cleared under 510(k) premarket notifications K181225, in the alkylene oxide copolymer carrier currently used in Baxter's ACTIFUSE SHAPE bone graft substitute, previously cleared under 510(k) premarket notification K082575. The hydroxyapatite granules used in ALTAPORE SHAPE, ALTAPORE, and ACTIFUSE SHAPE are all chemically identical. The intended use of the proposed product is the same as the predicate and reference device, and the fundamental technology of the device is the same across all three devices.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

ALTAPORE SHAPE is substantially equivalent to the predicate device previously cleared under 510(k) premarket notification, K181225 and the reference devices cleared under 510(k) premarket notifications K082575 and K140375. The function and intended use of the proposed device are equivalent to the predicate and reference devices. Table 3 provides a comparison of the technological characteristics of the proposed and predicate devices.

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Table 3. Technological Characteristics

Features	Predicate Device (K140375): MASTERGRAFT® Putty	Reference Device (K082575): ACTIFUSE SHAPE	Predicate Device (K181225): ALTAPORE	Proposed Device: ALTAPORE SHAPE
Composition	Calcium Phosphate Salt: Purified collagen of bovine origin and biphasic calcium phosphate ceramic. Type **I** bovine collagen. **15** percent hydroxyapatite and **85** percent β-tricalcium phosphate formulation.	Calcium Phosphate Salt: Silicate-substituted calcium phosphate composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).	Calcium Phosphate Salt: Silicate-substituted calcium phosphate composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).	Identical to Altapore predicate device and ACTIFUSE SHAPE refrence device.
Physical Structure	Granules with a natural, interconnected, porous structure which mimics the natural structure of bone.	Granules with a natural, interconnected, porous structure which mimics the natural structure of bone.	Granules with a porosity similar to cancellous bone.	Identical to Altapore (predicate) and Actifuse Shape (reference device).
Nominal (Total) Porosity	80% (interconnected porosity)	80 ± 2.5%	82.5 ± 2.5%	Identical to Altapore (predicate) and Actifuse Shape (reference device).
Strut Porosity	Information not publicly available.	Microporous	31-47%	Identical to Altapore (predicate).
Sterility	Irradiation	Irradiation	Irradiation	Identical to Altapore (predicate) and Actifuse Shape (reference device).

DISCUSSION OF NONCLINICAL TESTS

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results met the acceptance criteria, and support that the proposed devices are appropriately designed for their intended use.

Sterility

The ALTAPORE SHAPE device is sterilized with radiation. The minimum sterilizing dose (MSD) required to provide a 10^{-6} Sterility Assurance Level (SAL) for this (sub) category was established and validated at the manufacturing facility as described in ANSI/AAMI/ISO ISO 11137-2, "Sterilization of health care products- Radiation-Part 2: Establishing the Sterilization Dose."

These products are labeled "Sterile". Package Verification testing is based on Visual Inspection, Seal Strength, and Bubble Leak testing.

Shelf Life

Stability indicating parameters are identical between the reference device ACTIFUSE SHAPE and ALTAPORE SHAPE, as both are composed of the same materials and have identical packaging materials. A shelf life claim of 5 years is substantiated by stability results of the reference device ACTIFUSE SHAPE, (cleared under K082575).

Performance Testing- Bench

The microgranule phase of the proposed device and predicate device has identical chemical composition, physical structure, and manufacturing process and the carrier phase of the proposed device is identical to the chemical composition, packaging and sterilization methods . As such, no additional bench testing was conducted. All previous verification and validation testing performed for the predicate device, cleared under K181225, and testing performed for the ACTIFUSE SHAPE reference device, cleared under K082575, are applicable to the proposed product.

The following *in vitro* studies were conducted as part of the predicate submission to evaluate the performance characteristics of ALTAPORE SHAPE:

- Bioactive properties

Performance Testing- Animal

A preclinical animal study was conducted to evaluate the following performance characteristics of ALTAPORE SHAPE for use in the spine:

- Effectiveness for use in posterolateral fusion (with autogenous iliac crest bone graft (ICBG))

A preclinical animal study was carried out to assess the following performance characteristics of ALTAPORE SHAPE in extremities:

- Effectiveness for use in extremities (with and without autologous blood))

Biocompatibility

The hydroxyapatite microgranule phase in the proposed device has been used in the predicate device, ALTAPORE, with the same intended use and with the same type and duration of contact. ALTAPORE has been previously cleared under 510(k) submission, K181225.

The alkylene oxide copolymer carrier phase in the proposed device has previously been used in the reference device, ACTIFUSE SHAPE, with the same intended use and with the same type and duration of contact. ACTIFUSE SHAPE has been previously cleared under 510(k) submission, K082575.

Biocompatibility assessments were conducted based on ISO-10993-1 and FDA guidance *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 FDA guidance document, *Guidance for Industry and FDA Staff- Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device*. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- System Toxicity
- Pyrogen
- Genotoxicity
- Implantation

CONCLUSION

The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device and reference devices that are currently marketed for the same intended use.