May 8, 2020

Baxter Healthcare Corporation
Phillip Romei
Specialist, Global Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, Illinois 60073

Re: K200640
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: March 9, 2020
Received: March 11, 2020

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,

for

Jesse Muir, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200640

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, posterolateral spine and pelvis).
ALTAPORE SHAPE can be used by itself or with autograft as a bone graft extender in posterolateral spinal fusion procedures. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ALTAPORE SHAPE 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

March 03, 2020

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

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PREDICATE AND REFERENCE DEVICES:

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

Table 2. Predicate Devices

Device	Company	510(k)	Clearance Date
ALTAPORE (Predicate Device)	Baxter Healthcare Corporation	K192363	January 09, 2020
ALTAPORE SHAPE (Predicate Device)	Baxter Healthcare Corporation	K191513	October 19, 2019
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, posterolateral spine and pelvis).

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

Indications for Use statement is consistant with the recently cleared posterolateral spinal fusion procedure indication of the ALTAPORE predicate device (K192363), and the previously cleared use of ALTAPORE SHAPE as a bone void filler (K191513). Both ALTAPORE SHAPE and ALTAPORE consist of identical silicate-substituted calcium phosphate granules, and the differences in absorbable carrier phase do not alter the intended therapeutic use of the devices nor do they affect the safety and effectiveness of the device relative to the predicate or reference devices. Both the proposed and predicate devices have the same intended use for the treatment of filling bony voids or gaps of the skeletal system.

PURPOSE OF SUBMISSION

No material changes to ALTAPORE SHAPE have been made since the clearance of K191513.The purpose of this submission is to align the ALTAPORE SHAPE posterolateral spine fusion indications for use with that of the ALTAPORE predicate device previously cleared under K192363. The hydroxyapatite granules used in ALTAPORE SHAPE are identical to those in the predicate device ALTAPORE.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

ALTAPORE SHAPE is substantially equivalent to the predicate devices previously cleared under 510(k) premarket notification, K192363, K191513, and K140375. The function and intended use of the proposed device are equivalent to the predicate devices. Table 3 below 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	Predicate Device- (K191513): ALTAPORE SHAPE	Predicate Device (K192363): ALTAPORE	Proposed Device: ALTAPORE SHAPE
Chemical 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 phase: Phase-pure silicon-substituted hydroxylapatite $Ca_{10}(PO_4)_{(6-X)}(SiO_4)_{(X)}(OH)_{(2-X)}$ Silicon is present in 0.8 wt% amounts. Carrier: Absorbable Alkylene Oxide Co-polymer	Calcium Phosphate Salt phase: Phase-pure silicon-substituted hydroxylapatite $Ca_{10}(PO_4)_{(6-X)}(SiO_4)_{(X)}(OH)_{(2-X)}$ Silicon is present in 0.8 wt% amounts. Carrier: Absorbable Aqueous Gel	Calcium Phosphate Salt phase: Same as K192363 and K191513. Carrier Phase: Same as K191513.
Physical Structure	Granules with a natural, interconnected, porous structure which mimics the natural structure of bone.	Granules with a porosity similar to cancellous bone	Granules with a porosity similar to cancellous bone	Same as K191513, K192363, and K140375.
Nominal (Total) Porosity	80% (interconnected porosity)	82.5 ± 2.5%	82.5 ± 2.5%	Same as K191513, K192363, and K140375.
Strut Porosity	Information not publicly disclosed.	31-47%	31-47%	Same as K191513 K192363.
Sterility	Sterile, single use	Sterile, single use	Sterile, single use	Same as K191513, K192363, and K140375.
Sterilization Method	Irradiation	Irradiation	Irradiation	Same as K191513, K192363, and K140375.

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 to those previously cleared under the ALTAPORE SHAPE premarket notification K191513. A shelf life claim of 5 years is substantiated by stability results presented under K191513.

Performance Testing- Bench

The proposed device is identical to the ALTAPORE SHAPE predicate device cleared under K191513. As such, no additional bench testing was conducted. All previous verification and validation testing performed for the ALTAPORE SHAPE predicate device, cleared under K191513, 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 posterolateral spine fusion procedures as a bone graft extender. This study is presented again to support the performance of ALTAPORE SHAPE as a stand-alone bone graft substitute in posterolateral spinal fusion procedures:

- Effectiveness for use in posterolateral fusion

Biocompatibility

There are no changes to ALTAPORE SHAPE compared to the predicate device submission K191513. A summary of testing previously cleared under K191513 is included.

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 devices that are currently marketed for the same intended use.