January 9, 2020

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

Re: K192363
Trade/Device Name: ALTAPORE
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: August 26, 2019
Received: August 30, 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,

for

Laura Rose, 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)*
K192363

Device Name
ALTAPORE

Indications for Use *(Describe)*

ALTAPORE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). ALTAPORE can be used by itself, with autograft as a bone graft extender or with autogenous bone marrow aspirate. 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 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"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."*

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## 510(k) Summary

**OWNER:**

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

**CONTACT PERSON:**

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Specialist, Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: (224) 948-2652
Fax: (224) 270-4119

**IDENTIFICATION OF THE DEVICE:**

**Common Name:** Bone Void Filler
**Trade/Device Name:** ALTAPORE
**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 |
|---|---|
| 1504319 | ALTAPORE, 1.5 ml |
| 1504320 | ALTAPORE, 2.5 ml |
| 1504321 | ALTAPORE, 5 ml |
| 1504322 | ALTAPORE, 10 ml |
| 1504323 | ALTAPORE, 20 ml |

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**PREDICATE DEVICES:**

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

**Table 2. Predicate Devices**

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

The proposed device is substantially equivalent to the predicate and reference devices, ALTAPORE and MASTERGRAFT® Putty. The reference device, MASTERGRAFT® Putty, supports posterolateral spinal use with or without mixing with autologous bone or Bone Marrow Aspirate (BMA) with the proposed product. The proposed and predicate devices have identical chemical composition, physical structure, packaging, sterilization, and manufacturing process.

**DESCRIPTION OF THE DEVICE:**

ALTAPORE 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 is similar to human cancellous bone and is intended to support bone growth with macro and micro- porosity. ALTAPORE is composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).

ALTAPORE is supplied in a sterile applicator and contains ALTAPORE microgranules, sized 1-2 mm, 80-85% total porosity, suspended in an absorbable aqueous gel carrier. ALTAPORE does not set in-situ following implantation. ALTAPORE is available in 1.5 ml, 2.5 ml, 5 ml, 10 ml, and 20 ml configurations.

ALTAPORE is designed for use as a standalone bone graft substitute or as an autograft extender. While not necessary, the product can be mixed with Bone Marrow Aspirate (BMA) or autologous bone at the discretion of the surgeon.

ALTAPORE 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 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 undergoes cell-mediated remodeling and is replaced by natural bone.

**INDICATIONS FOR USE**

ALTAPORE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). ALTAPORE can be used by itself, with autograft as a bone graft extender or with autogenous bone marrow aspirate. 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 resorbs and is replaced with bone during the healing process.

The Indications for Use statement for the ALTAPORE device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device 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.

**TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

ALTAPORE is substantially equivalent to the predicate and reference devices previously cleared under 510(k) premarket notifications, K181225 and K140375. The function and intended use of the proposed device are equivalent to the predicate 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 (K181225): ALTAPORE | Reference Device (K140375): MASTERGRAFT® Putty | Proposed Device: ALTAPORE |
|---|---|---|---|
| Composition | 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: Purified collagen of bovine origin and biphasic calcium phosphate ceramic. Type **I** bovine collagen. **15** percent hydroxyapatite and **85** percent β-tricalcium phosphate formulation. | Identical to predicate. |
| Physical Structure | Granules with a porosity similar to cancellous bone. | Granules with a natural, interconnected, porous structure which mimics the natural structure of bone. | Identical to predicate and reference device. |
| Nominal (Total) Porosity | 82.5 ± 2.5% | 80% (interconnected porosity) | Identical to predicate and reference device. The nominal total porosity of the primary predicate falls within the range of the proposed device |
| Strut Porosity | 31-47% | Information not publicly available. | Identical to predicate device. |
| Shelf Lfie | 24 months | Information no publically available | Identical to predicate device |
| **Sterlization** | | | |
| Sterility | Sterile, Single Use | Sterile, Single Use | Identical to predicate and reference devices. |
| Method | Irradiation | Irradiation | Identical to predicate and reference devices. |
| Sterilization Standard Compliance | ISO 11137, SAL = $10^{-6}$ | Information not publicly available | Identical to the predicate device. Information on compliance standards used for the reference device is not publicly disclosed. |

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## 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.

### Performance Testing- Bench

The proposed device and predicate device have an identical chemical composition, physical structure, packaging, sterilization, and manufacturing process. As such, no additional bench testing was conducted since the two devices are identical in physical composition. All previous verification and validation testing performed for the predicate device, cleared under K181225, is still applicable to the proposed product.

The following *in vitro* studies were previously conducted as part of the predicate submission (K181225) to evaluate the performance characteristics of ALTAPORE:

- Dissolution properties

Testing of dissolution was performed in accordance with ISO 10993-14: Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics.

- Bioactive properties

An *In Vitro* Bioactivity Study was conducted to evaluate the amount of hydroxycarbonate apatite (HCA) formation on granular ceramic bone graft after submersion in simulated body fluid at a specific temperature at a range of different time periods.

### Performance Testing- Clinical

A single-arm, prospective clinical study was conducted which supports the safety and effectiveness of ALTAPORE in posterolateral fusion without mixing the proposed device with Bone Marrow Aspirate (BMA) or autograft bone.

Patients with degenerative disc disease, spondylolisthesis or spinal stenosis underwent PLF surgery with ALTAPORE. The primary endpoint was evaluated in the per protocol population (N = 102) as solid fusion at postoperative month 12 assessed using computed tomography (CT) scans, with motion assessed using flexion–extension radiographs. Clinical outcomes included the Oswestry Disability Index, 36-item short-form health survey for quality-of-life, visual analog scale for painscores and neurological assessments. Adverse events were recorded.

Successful fusion was achieved in 59/89 (66.3%) patients at month 6, 88/102 patients (86.3%) at month 12 (primary endpoint) and 87/96 (90.6%) patients at month 24. Following surgery, levels of disability and pain improved from baseline. Quality-of-life improved and neurological function was maintained postoperatively. Forty-three (33.3%) of the 129 patients who underwent surgery experienced adverse events; back pain was most frequent ($n$ = 10); nine and 14 patients experienced serious adverse events judged related to device and procedure, respectively. This study supports the use of Altapore as a stand-alone device in PLF surgeries.

**Biocompatibility**

All materials in the proposed device have 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.

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
- Genotoxicity, Carcinogenicity, and Reproductive Toxicity
- Implantation

ALTAPORE is non-pyrogenic based on material-mediated Pyrogenicity testing conducted per ISO 10993-11 and bacterial endotoxin testing performed per USP<85> .

**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. The clinical date demonstrate that the subject device is safe and effective for use in the posterolateral fusion of the spine without the need for any additional material (e.g., autograft or BMA).