August 2, 2024

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

Re: K241564
Trade/Device Name: Actifuse ABX; Actifuse MIS; Actifuse Shape; ALTAPORE; ALTAPORE SHAPE; ALTAPORE MIS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 22, 2024
Received: May 31, 2024

Dear Phillip 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert M. Stefani -S
2024.08.02 09:17:50 -04'00'

For: Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241564

Device Name

Actifuse ABX;
Actifuse MIS;
Actifuse Shape;
ALTAPORE;
ALTAPORE SHAPE;
ALTAPORE MIS

Indications for Use *(Describe)*

ACTIFUSE ABX, ACTIFUSE SHAPE and ACTIFUSE MIS:
Actifuse™ is a bone void filler intended only for orthopaedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral fusion procedures with appropriate stabilizing hardware and intervertebral disc space. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

When used in the intervertebral disc space, Actifuse must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

ALTAPORE:
ALTAPORE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, 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.

When used in the intervertebral disc space, ALTAPORE must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

ALTAPORE SHAPE:
ALTAPORE SHAPE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, 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.

When used in the intervertebral disc space, ALTAPORE SHAPE must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

ALTAPORE MIS:
ALTAPORE MIS is an implant intended to fill bony voids or gaps of the skeletal system (i.e.,

extremities, posterolateral spine, intervertebral disc space, and pelvis).

ALTAPORE MIS 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 MIS resorbs and is replaced with bone during the healing process.

When used in the intervertebral disc space, ALTAPORE MIS must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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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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

Device Trade Name:	ACTIFUSE ABX, ACTIFUSE SHAPE, ACTIFUSE MIS ALTAPORE ALTAPORE SHAPE ALTAPORE MIS
Manufacturer:	Baxter Healthcare Corporation One Baxter Parkway Deerfield, Illinois 60015
Contact:	Phillip Romei Specialist, Regulatory Affairs 25212 W. Illinois Route 120 Round Lake, IL 60073
Prepared by:	Justin Eggleton, Vice President, Head of Musculoskeletal Regulatory Affairs MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	May 22, 2024
Classifications:	21 CFR §888.3045, Resorbable Calcium Salt Bone Void Filler Device
Class:	II
Product Codes:	MQV
Primary Predicate:	Catalyst Bone Void Filler, OssDsign AB, K232315
Reference Devices:	Actifuse ABX, Actifuse Shape, & Actifuse MIS, Baxter, K082575 Altapore, Baxter, K192363 Altapore Shape, Baxter, K200640 Altapore MIS, Baxter, K201464

Indications For Use:

ACTIFUSE ABX, ACTIFUSE SHAPE, ACTIFUSE MIS

Actifuse™ is a bone void filler intended only for orthopaedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral fusion procedures with appropriate stabilizing hardware and intervertebral disc space. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

When used in the intervertebral disc space, Actifuse must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

ALTAPORE

ALTAPORE is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, intervertebral disc space, 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.

When used in the intervertebral disc space, ALTAPORE must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

ALTAPORE SHAPE

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

When used in the intervertebral disc space, ALTAPORE SHAPE must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

ALTAPORE MIS

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

ALTAPORE MIS 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 MIS resorbs and is replaced with bone during the healing process.

When used in the intervertebral disc space, ALTAPORE MIS must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Device Description:

ACTIFUSE ABX, ACTIFUSE SHAPE, ACTIFUSE MIS

Actifuse is a phase-pure, porous, silicate-substituted calcium phosphate osteoconductive bone void filler, comprising a single-phase calcium phosphate scaffold, either granules or granules delivered in a matrix of resorbable polymer. 0.8wt% silicon (Si) is incorporated into the crystalline structure. The interconnected and open porous structure of Actifuse is similar to human cancellous bone. After it is implanted, ACTIFUSE undergoes physiologically-mediated resorption and is replaced by natural bone

ACTIFUSE is osteostimulatory based upon in vitro studies that show cellular responses, such as metabolic activity and proliferation, are accelerated when compared to an identical material that did not contain 0.8% silicon by weight..

ACTIFUSE 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.

ACTIFUSE 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.

The Actifuse bone void filler is presented in multiple product variants:

<u>ACTIFUSE ABX</u>

ACTIFUSE ABX presents the ACTIFUSE bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler suspended in an absorbable aqueous gel carrier packaged in a wide-bore applicator. ACTIFUSE ABX is a sterile, single-use device available in volumes of 1.5 ml, 2.5 ml, 5 ml, 10 ml, and 20 ml.

ACTIFUSE ABX 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, autologous bone marrow aspirate, or autologous bone at the discretion of the surgeon.

<u>ACTIFUSE MIS</u>

ACTIFUSE MIS System is an ACTIFUSE ABX packaging configuration in which the ACTIFUSE ABX implant material is supplied in a sterile 7.5ml. The 7.5ml cartridge packed with ACTIFUSE ABX implant material is presented with a delivery applicator and as a separate 7.5ml refill cartridge.

ACTIFUSE SHAPE

ACTIFUSE SHAPE supplies the ACTIFUSE bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler suspended in an absorbable Alkylene Oxide co-polymer carrier as a shaped wax-like putty in a sterile pouch. ACTIFUSE SHAPE is available as a 1.6 ml small cylinder, 2.6 ml medium cylinder, 8 ml large cylinder, and 15.8 ml large strip.

ACTIFUSE 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

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.

ALTAPORE MIS

ALTAPORE MIS System is an ALTAPORE packaging configuration in which the ALTAPORE implant material is supplied in a sterile 7.5ml. The 7.5ml cartridge is presented with a delivery applicator and as a separate 7.5ml refill cartridge.

ALATAPORE MIS System (hereafter referred to as “Altapore MIS) 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 MIS 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

ALTAPORE SHAPE supplies the ALTAPORE bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler suspended in an absorbable Alkylene Oxide co-polymer carrier as a shaped wax-like putty in a sterile pouch. ALTAPORE SHAPE 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.

Predicate Device:

Baxter submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Baxter Bone Void Fillers are substantially equivalent in intended use, indications, basic design, function, and performance to the following predicate device, which has been determined by FDA to be substantially equivalent to pre-amendment device:

Primary Predicate:	Catalyst Bone Void Filler, OssDsign AB, K232315

Reference Device(s):

Baxter submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Baxter ACTIFUSE ABX, ACTIFUSE SHAPE, ACTIFUSE MIS, ALTAPORE, ALTAPORE SHAPE, and ALTAPORE MIS Bone Void Fillers are substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Reference Device:	Actifuse ABX, Actifuse Shape, & Actifuse MIS, Baxter, K082575 Altapore, Baxter, K192363 Altapore Shape, Baxter, K200640

Altapore MIS, Baxter, K201464

Performance Testing Summary:
The purpose of this submission is to expand the indications for use of the Baxter Bone Void Filler devices to include use in the intervertebral disc space in conjunction with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Because the subject device is identical to the previously cleared primary predicate device (K232315), it was determined that no additional non-clinical data was needed to support the expanded indications proposed in the current submission.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Baxter ACTIFUSE ABX, ACTIFUSE SHAPE, ACTIFUSE MIS, ALTAPORE, ALTAPORE SHAPE, and ALTAPORE MIS Bone Void Fillers are as safe, as effective, and performs as well as the predicate devices.