August 17, 2018

Baxter Healthcare Corporation
Daniel Davis
Senior Manager, Global Regulatory Affairs
32650 North Wilson Road
Round Lake, Illinois 60073

Re: K181306
Trade/Device Name: Actifuse™ Flow
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 18, 2018
Received: July 20, 2018

Dear Mr. Davis:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181306

Device Name
Actifuse ™ Flow

Indications for Use *(Describe)*
Actifuse™ Flow is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse™ Flow can be injected into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. 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.

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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"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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Section 5. 510(k) Summary

May 22, 2018

OWNER:

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

CONTACT PERSON:

Daniel Davis
Senior Manager, Global Regulatory Affairs
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Round Lake, IL 60073
Telephone: (224) 948-3775
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IDENTIFICATION OF THE DEVICE:

Common Name: Filler, bone void, calcium compound
Trade Name: Actifuse™ Flow Bone Graft Substitute
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV

Table 1. Model Numbers for Actifuse™ Flow

Model Number	Name
506005078076	Actifuse Flow Bone Graft Substitute, 1.5ml
506005078077	Actifuse Flow Bone Graft Substitute, 3.0ml
506005078078	Actifuse Flow Bone Graft Substitute, 5.0ml

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PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Actifuse™ Flow Bone Graft Substitute	ApaTech Limited 370 Centennial Avenue Elstree, Hertfordshire WD6 3TJ United Kingdom.[1]	K082073	September 11, 2008

[1] ApaTech Limited was acquired by Baxter Healthcare Corporation in 2010

Table 3. Reference 510(k)

Device	Company	Reference 510(k)	Clearance Date
Actifuse™ Flow Bone Graft Substitute, Actifuse™ Shape Bone Graft Substitute, Actifuse™ ABX E-Z fil Putty, Actifuse™ Bone Graft Substitute	ApaTech Limited 370 Centennial Avenue Elstree, Hertfordshire WD6 3TJ United Kingdom.[1]	K081979	November 6, 2008
Altapore™ Bone Graft Substitute	ApaTech Limited 370 Centennial Avenue Elstree, Hertfordshire WD6 3TJ United Kingdom.[1]	K130531	April 8, 2014
Actifuse™ ABX E-Z fil Putty Bone Graft Substitute	ApaTech Limited 370 Centennial Avenue Elstree, Hertfordshire WD6 3TJ United Kingdom.[1]	K071206	May 31, 2007
Actifuse™ Bone Graft Substitute Actifuse™ Microgranules Bone Graft Substitute ActifuseTM E-Z-Prep Actifuse™ ABX Bone Graft Substitute Actifuse TM MIS Actifuse™ Shape Bone Graft Substitute Actifuse™ Flow Bone Graft Substitute	ApaTech Limited 370 Centennial Avenue Elstree, Hertfordshire WD6 3TJ United Kingdom.[1]	K090850	July 30, 2009

[1] ApaTech Limited was acquired by Baxter Healthcare Corporation in 2010

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DESCRIPTION OF THE DEVICE:

Actifuse™ Flow Bone Graft Substitute 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™ Flow Bone Graft Substitute can be injected into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. 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.

Actifuse™ Flow is phase-pure silicon-substituted calcium phosphate osteoconductive bone void filler, comprising a single-phase calcium phosphate scaffold delivered in a matrix of resorbable polymer. The interconnected and open porous structure inherent of the source material for the mineral phase of Actifuse™ Flow is similar to human cancellous bone.

INDICATIONS FOR USE:

Actifuse™ Flow is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse™ Flow can be injected into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. 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.

PURPOSE OF SUBMISSION:

The basis for this premarket notification is modifications to the Actifuse™ Flow product line. The modifications consist of applicator syringe design changes (both material and dimensional changes) to create a ready-to-use version of the Actifuse™ Flow device. The proposed new applicator syringe materials are currently used in Baxter's Altapore and Actifuse™ ABX Bone Graft substitute product lines and have been previously cleared under 510(k) premarket notifications K130531 (cleared date 8th Apr, 2014) and K071206 (cleared date 31st May, 2007) respectively. The hydroxyapatite granules used in Actifuse ABX, Actifuse Flow, and Altapore are all chemically identical. These modifications do not impact the intended use or the fundamental technology of the devices.

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TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices have equivalent technological characteristics as Baxter's currently cleared Actifuse™ Flow product line, cleared under 510(k) premarket notification K082073 (cleared September 11, 2008).

DISCUSSION OF NON-CLINICAL DATA:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the proposed devices are appropriately designed for their intended use. All testing was performed on the configuration of the devices presented in this premarket notification.

Performance Data

The performance of the Actifuse™ Flow device after modifications made to the applicator syringe was assessed by analyzing the Actifuse™ Flow final product for chemical changes relative to the predicate product's specification. All testing confirmed that the modifications had no impact to the chemistry or structure of the Actifuse™ Flow product.

Biocompatibility

All materials found in these devices that are the subject of this submission have been previously cleared under Baxter's 510(k) premarket notifications K082073 (clearance date September 11, 2008), K130531 (clearance date April 8, 2014) and K071206 (clearance date 31st May, 2007).

Biocompatibility assessments were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for permanent duration, implant device, tissue/bone contact, 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 "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA".

Sterility

The Actifuse™ Flow product line 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

Baxter has performed aging testing to support a shelf-life claim of two (2) years.

CONCLUSION:

Actifuse™ Flow Bone Graft Substitute is as safe and effective as the predicate Actifuse™ Flow Bone Graft Substitute. Both devices share indications for use, technological characteristics, and principles of operation. The only differences between the two devices are the changes to the dimensions and materials of the syringes housing the devices. The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device.