

Premarket Notification [510(k)] Summary
(per 21 CFR 807.92)

K081979

NOV - 6 2008

Submitter: ApaTech Limited
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Centennial Park
Elstree, Hertfordshire WD6 3TJ
United Kingdom

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Date Prepared: October 27, 2008

Classification: Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Controls per 21 CFR 888.3045, Product Code MQV.

Trade Name: Actifuse™ Bone Graft Substitute
Actifuse™ ABX E-Z-fil Bone Graft Substitute
Actifuse™ Shape Bone Graft Substitute
Actifuse™ Flow Bone Graft Substitute

Common Name: Bone Void Filler

Intended use:

Actifuse™, Actifuse™ ABX E-Z-fil Putty, Actifuse™ Shape

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. 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

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.

Device Description

Actifuse™ is a bioactive phase-pure silicon-substituted calcium phosphate osteoconductive and osteostimulative bone void filler, comprising a single-phase calcium phosphate scaffold, either granules or granules delivered in a matrix of resorbable polymer. The interconnected and open porous structure of the calcium phosphate phase of Actifuse is similar to human cancellous bone.

Technological Characteristics and Substantial Equivalence

Actifuse™ is composed of a porous calcium salt equivalent to that contained in the predicate device and to that in routine clinical use. The technologies employed in Actifuse™ and its predicate device are therefore substantially equivalent. Actifuse™ has the same indications, contraindications, risks and potential adverse events as the predicate device and thus substantial equivalence is claimed for the device.

Testing

Testing has shown Actifuse™ to meet the requirements of all relevant standards for Calcium Salt Bone Void Fillers. Testing has confirmed Actifuse™ to be safe and effective in providing a scaffold for rapid bone repair via bony infiltration of the porous scaffold.

Actifuse is bioactive based on *in-vitro* studies in which growth of an apatite layer was induced on the surface of Actifuse following exposure to simulated body fluid. The time required to form a new apatite layer on the surface of Actifuse was reduced by 29% when compared to an identical calcium phosphate material that did not contain 0.8wt% silicate.

Actifuse is found to be osteostimulatory based on cell culture studies that showed that cellular responses, such as metabolic activity and proliferation, were accelerated when compared to an identical material that did not contain 0.8wt% silicate.

These results demonstrate that Actifuse is a scaffold supporting rapid bone formation. The bioactive and osteostimulatory nature of Actifuse has not been correlated with human clinical experience.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 - 2009

Apatech Ltd
% Ms. Candace F. Cederman
15058 Armel Drive
Oregon City, Oregon 97045

Re: K081979

Trade Name: Actifuse™ Bone Graft Substitute, Actifuse™ ABX E-Z-FIL, Actifuse™
Shape Bone Graft and Actifuse™ Flow Bone Graft Substitute

Regulation Number: 21 CFR 888.3045

Regulation Name: Resorbable calcium salt bone void filler device

Regulatory Class: II

Product Code: MQV

Dated: July 10, 2008

Received: July 11, 2008

Dear Ms. Cederman:

This letter corrects our substantially equivalent letter of November 6, 2008.

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications for Use

510(k) Number (if known): K081979

Device Name: Actifuse™ Flow Bone Graft Substitute

Indications for Use:

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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Statement of Indications for Use

510(k) Number (if known): K081979

Device Name: Actifuse™ Shape Bone Graft Substitute

Indications for Use:

Actifuse™ Shape 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. 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

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Indications for Use

510(k) Number (if known): K081979

Device Name: Actifuse™ ABX E-Z-fil Putty

Indications for Use:

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. 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

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AND/OR

Over-The-Counter Use _____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Indications for Use

510(k) Number (if known): K081979

Device Name: Actifuse™ Bone Graft Substitute

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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Concurrence of CDRH, Office of Device Evaluation (ODE)