K082575

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

NOV 25 2008

Submitter:

ApaTech Limited
370 Centennial Avenue
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United Kingdom

Contact Person:

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Date Prepared: 3 September 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™ Microgranules Bone Graft Substitute
Actifuse™ E-Z Prep
Actifuse™ ABX E-Z-fil Bone Graft Substitute
Actifuse™ MIS
Actifuse™ Shape Bone Graft Substitute

Common Name: Bone Void Filler

Intended 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.

Device Description

Actifuse is a phase-pure 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.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2008

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

Re: K082575
Trade/Device Name: Actifuse™ Bone Graft Substitute, Actifuse™ Microgranules Bone Graft Substitute, Actifuse™ E-Z Prep, Actifuse™ ABX E-Z fil Bone Graft Substitute, Actifuse™ MIS, Actifuse™ Shape 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: September 3, 2008
Received: September 5, 2008

Dear Ms. Cederman:

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. 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 such 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 begin 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) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Statement of Indications for Use

510(k) Number (if known): K082575

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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

510(k) Number K082575