

510(k) Summary

K103036

Submitted by: AlloSource®
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Contact Person: Pamela L. Vetter

Date Prepared: January 4, 2011

Proprietary Name: AlloFuse® Plus Paste and AlloFuse® Plus Putty

Common Name: Bone Void Filler

Classification Name: Resorbable calcium salt bone void filler device
(21 CFR 888.3045)
MQV, MBP

Predicate Device(s): OrthoBlast® II
510(k) # K070751, K050642

AlloFuse Gel and Putty
510(k)# K071849

JAN 10 2011

Device Description:

AlloFuse Plus is derived from selected donated human bone tissue that has been processed into particles. The bone particles are subsequently demineralized using a hydrochloric acid process. The demineralized bone matrix (DBM) is combined with a reverse phase carrier, cancellous chips from the same donor and formulated into a paste or putty-like consistency.

The carrier is a solution of polyethylene oxide polypropylene oxide block copolymer dissolved in water exhibiting reverse phase characteristics (i.e. an increase in viscosity as temperature increases).

Intended Use of Device:

For orthopedic use, AlloFuse Plus Paste and Putty are intended for use as an autograft extender (i.e. extremities, posterolateral spine and pelvis) and as a bone void filler (i.e. extremities and pelvis) for bony voids or gaps that are not intrinsic to the stability of the bony structure. The AlloFuse Plus products are indicated to be packed gently into bony defects of the skeletal system. These defects may be surgically created or from the result of traumatic injury to the bone.

Technological Characteristics and Substantial Equivalence:

The proposed device is the same device in design, materials of construction and function as the previously cleared devices of 510(k) Notification K070751 cleared 15-Oct-2007 and K050642 cleared 05-Dec-2005. Through a contractual agreement with IsoTis Orthobiologics, AlloSource received an exclusive license to use the intellectual property necessary to manufacture the predicate device in North America and a non-exclusive license to market the predicate device worldwide under the AlloFuse Plus name or that of private label partners.

The proposed and predicate devices are osteoconductive and exhibit osteoinductive potential.

Viral Inactivation Validation:

The methods for processing the DBM and cancellous chips contained in AlloFuse Plus were evaluated for their viral inactivation potential as well as the electron beam sterilization process for final product. A select panel of viruses representing various virus types, sizes, shapes, and genomes was evaluated. Both the DBM processing method (demineralization), the proprietary cleaning process for the cancellous bone and the sterilization process were determined to provide significant viral inactivation potential for a wide range of potential human viruses.

Osteoinductive Potential:

AlloFuse Plus Paste and Putty have been shown to have osteoinductive potential in athymic rats. Every lot of final product is tested via an *in vivo* assay to ensure osteoinductive potential of the final product. Osteoinduction assay results in the athymic rat model should not be interpreted to predict clinical performance in human subjects.

Product Performance Data:

Product safety and effectiveness is adequately supported by the substantial equivalence information and test data including osteoinductive potential, viral inactivation and endotoxin/LAL provided in this Premarket Notification.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

AlloSource
c/o Ms. Pamela L. Vetter
Regulatory Affairs Manager
6278 South Troy Circle
Centennial, Colorado 80111

JAN 10 2011

Re: K103036

Trade/Device Name: AlloFuse Plus Paste and AlloFuse Plus Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: October 11, 2010
Received: October 13, 2010

Dear Ms. Vetter:

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 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800)-638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

*For Peter R. Melkerson
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Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

