

K071849

DEC 04 2008

Traditional 510(k)  
AlloFuse® Gel and Putty

### 510(k) Summary

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Submitted by: AlloSource  
6278 S. Troy Circle  
Centennial, CO 80111 USA  
Telephone: 720-873-0213  
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Contact Person: Pamela L. Vetter

Date Prepared: December 1, 2008

Proprietary Name: AlloFuse® Gel and AlloFuse® Putty

Common Name: Bone Void Filler

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

Predicate Device: DynaGraft® II K040419  
AlloMatrix® Putty K041168

**Device Description:** AlloFuse® 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 an inert reverse phase carrier and formulated into a gel 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 applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. AlloFuse® is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine, and pelvis) and as bony void filler of the extremities and pelvis. 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 K040419 cleared 25-March-2005. Through a contractual agreement with IsoTis Orthobiologics, AlloSource receives 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® name or that of private label partners.

The proposed and predicate devices are osteoconductive and osteoinductive. AlloFuse® and DynaGraft® II provide an interconnected, porous scaffold and an environment for new bone in-growth and stimulate bone growth. All products are provided sterile and for single patient use. The donor bone in the AlloFuse® product meets the requirements of the American Association of Tissue Banks (AATB). Product safety and effectiveness are adequately supported by the substantial equivalence information, materials data, and test results provided in this Premarket Notification.

#### Viral Inactivation Validation

The method for processing the DBM contained in AlloFuse® was evaluated for its viral inactivation potential. A select panel of viruses representing various virus types, sizes, shapes, and genomes was evaluated. The DBM processing method was determined to provide significant viral inactivation potential for a wide range of potential human viruses.

#### Osteoinductive Potential

AlloFuse has 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 Testing

Performance of DBM in a reverse phase medium (RPM) carrier in accordance with the DynaGraft® II Gel and Putty formulations has been evaluated in rabbit and sheep models by radiographic and histological methods for the indications specified in the Premarket Notification.

Clinical studies using the predicate device (DynaGraft® II DBM Putty and Gel) have been performed for spinal fusions demonstrating acceptable outcomes.

Because AlloFuse® is the same device in design, materials and function as the predicate device these data substantiate AlloFuse® Putty and Gel safety and effectiveness for the indications presented in this Premarket Notification.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 04 2008

AlloSource, Inc.  
% Ms. Pamela Vetter  
Sr. Regulatory Affairs Specialist  
6278 S. Troy Circle  
Centennial, Colorado 80111

Re: K071849

Trade Name: AlloFuse® GEL and AlloFuse® Putty  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: II  
Product Code: MBP, MQV  
Dated: September 22, 2008  
Received: September 24, 2008

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 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.

Page 2 – Ms. Pamela Vetter

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" (21 CFR 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 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

## Indications for Use

510(k) Number (if known): K071849

Device Name: ALLOFUSE® GEL AND ALLOFUSE® PUTTY

Indications for Use:

AlloFuse® is indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. AlloFuse® is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine, and pelvis) and as bony void filler of the extremities and pelvis. These defects may be surgically created or from the result of traumatic injury to the bone.

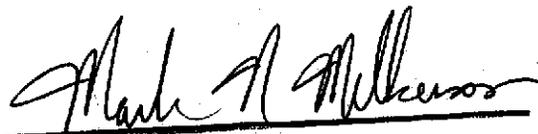
Prescription Use X  
(21 CFR 801 Subpart D)

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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