

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

Submitted by: Bone Solutions, Inc.
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Date Prepared: May 4, 2009

Proprietary Name: OsteoCrete™ Bone Void Filler

Common Name: Resorbable calcium salt bone void filler device

Classification: Class II, MQV, 21 CFR 888.3045

Predicate Devices: **Synthes (USA).** Norian SRS Bone Void Filler, 510(k) number K011897
Synthes (USA). Norian SRS Fast Set Putty, 510(k) number K041842
Futura Biomedical. OsteoCure Resorbable Bead Kit, 510(k) number K051406
Bone Support AB. Cerament Bone Void Filler, 510(k) number K051951

Device Description: **OsteoCrete™** is an injectable, moldable, and biocompatible Bone Void Filler. The OsteoCrete™ Bone Void Filler Packet contains powder (Magnesium based compound) and a mixing solution (Buffered saline). It is a sterile, single use device, packaged with mixing and administration tools.

Indication for Use: Bone Solutions, Inc., OsteoCrete™ Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Bone Solutions, Inc.,

OsteoCrete™ Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (the long bones and pelvis). 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 with bone during the healing process.

Performance Data: OsteoCrete™ Bone Void Filler was subjected to performance testing (bench and animal) in accordance with the FDA Guidance Document, “Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler; Guidance for Industry and FDA.” The testing confirmed substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bone Solutions Incorporated
% Mr. Tony Copp
Director, Executive Vice President, Chief Operating Officer
9400 North Central Expressway, Suite 1250
Dallas, Texas 75231

MAY 21 2009

Re: K071004
Trade/Device Name: OsteoCrete™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 26, 2008
Received: August 28, 2008

Dear Mr. Copp:

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.

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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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its 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", with a long horizontal flourish extending to the right.

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

Enclosure

Request for additional information from the FDA to Bone Solutions regarding K071004.

Indications for Use

510(k) Number (if known): K071004

Device Name: Bone Solutions, Inc. OsteoCrete™ Bone Void Filler

Indications for Use:

Bone Solutions, Inc., OsteoCrete™ Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Bone Solutions, Inc., OsteoCrete™ Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (the long bone and pelvis). 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 with bone during the healing process. OsteoCrete™ Bone Void Filler is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K071004

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