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Section 6

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Sponsor/Applicant Number	Biomet 3i 4555 Riverside Drive Palm Beach Gardens, Florida 33410 1-800-342-5454 Fax: 561-514-6316 www.biomet3i.com
Establishment Registration	1038806
Sponsor/Applicant Contact	Mayank Choudhary Regulatory Affairs Specialist Mayank.choudhary@biomet.com 561-776-6831
Date Prepared	December 10, 2012
Preparer	Biomet Interpore Cross 181 Technology Drive Irvine, California 92618 949-453-3200 Fax: 949-453-3225 Establishment Number: 2029012
Contact for Review/Questions	Kathleen Olivares, Regulatory Affairs Associate Kathleen.olivares@biomet.com 949-453-3200, extension 104
Trade/Proprietary Name	RegenerOss Allograft Putty Plus Mineralized
Common/User Name	Demineralized Bone Matrix (DBM) with Mineralized Cancellous Chips in a Lipid Carrier
Classification Name	Class II
Legally Marketed Devices to Which Substantial Equivalence is Claimed	510(k) K070147- InterGro Oral
Other Marketed Devices in the Same	510(k) K080418- Regenaform; Altiva DBM with Cortical

K113645

Classification Using Cancellous Bone Chips	Cancellous Chips; Regeneration Technologies Inc. 510(k) K060332- OrthoBlast II DBM Paste and Putty with Cancellous Chips; IsoTis OrthoBiologics, Inc.
Description of the Device	Bone Filling Material used for augmenting deficient bone or filling bone defects in oral/dental applications. Allograft (Bone) Putty containing human allograft bone tissue (DBM) and mineralized cancellous chips, from the same donor, combined with a lipid carrier.
How the Device Functions	A resorbable, osteoconductive bone graft substitute with osteoinductive potential that promotes bone formation. The implant is resorbed and is replaced with bone during the healing process.
Scientific Concepts and Significant Characteristics	Demineralized cortical bone matrix, (DBM) is derived from donated human tissue allograft bone which has been granulated, demineralized, and lyophilized and contains various growth factors including osteoinductive proteins. Mineralized cancellous bone chips from the same donor as the DBM are added for radiopacity, osteoconduction, and to enhance the structural strength of the product. An added carrier is a resorbable, biocompatible, semi-viscous lipid. By combining the DBM and cancellous chips with the carrier it allows for easier intra-operative handling and improves holding properties of the DBM at the site of transplantation.
Intended Use of the Device	The indication for use statement is the same as the predicate device, InterGro Oral, legally marketed by Biomet 3i. RegenerOss Allograft Putty Plus Mineralized is a bone filling material indicated for dental intraosseous and oral/maxillofacial defects including:localized ridge augmentations, extraction sockets, cystic defects, sinus lifts, peri-implant defects, defects associated with root resection or apicoectomy, and periodontal defects.
Summary of New Device Comparison to Predicate Device	The technological characteristics of the new device are the same in comparison to those of the predicate. RegenerOss Allograft Putty Plus Mineralized Cancellous Bone Chips is a modification of a Biomet cleared device, InterGro Oral. The difference between the two devices, or change, is to a secondary material ingredient. For marketing purposes one source of calcium salt granules, a hydroxyapatite material

	(Pro Osteon), is being replaced with another source of calcium salt or hydroxyapatite material, Cancellous Bone Chips, from the same donor as the DBM. The use of cancellous bone chips serves the same purpose as the Pro Osteon calcium salt granules, to improve the radiopacity, osteoconduction, and structural strength of the product. Cancellous Bone Chips are legally marketed in other devices within the same classification regulation, for the same intended use.
Substantial Equivalence	A rigorous design control process is the basis for a substantial equivalence determination. This well defined modification to the currently marketed Biomet device followed a predetermined set of requirements and activities in the management of the design and development of the product. The process included documentation of design inputs, risk analysis, design output, test procedures, generation and completion of verification and validation steps, and the completion and documentation of formal design reviews. All verification and validation activities have been performed successfully, as identified by the risk analysis, ensuring the modified device is as safe and effective as the predicate device. The predetermined acceptance criteria have been met.
Non-Clinical Studies	Additional testing was performed in accordance with the risk analysis and design control process to characterize RegenerOss Allograft Putty plus Mineralized and to demonstrate substantial equivalence to the predicate device. Osteoinductive potential of the modified device compared to the predicate device has been evaluated in the athymic rat ectopic bone growth model. Results indicate comparable levels of osteoinductive performance (as indicated by histological scoring of new bone formation) of the predicate device compared to the modified device in this model. Product functional testing was performed, including solubility testing in an aqueous environment and handling evaluation (extrudability, moldability and disintegration). Results indicate that the solubility and handling characteristics of the modified device are comparable to that of the predicate device.

Conclusion	**The safety and effectiveness of RegenerOss Allograft Putty Plus Mineralized was verified and documented through Biomet's design control process. Substantial equivalence to the predicate device is based on the same intended use and base material, (DBM and Carrier) of the Biomet cleared device, Intergro Oral; use of a secondary material ingredient cleared as part of other legally marketed devices within the same classification and same intended use; and verification and validation of selected performance properties and acceptance criteria.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Kathleen Olivares
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Biomet Interpore Cross
181 Technology Drive
Irvine, California 92618

JAN 2 0 2012

Re: K113645
Trade/Device Name: RegenerOss Allograft Putty Plus Mineralized
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: January 18, 2012
Received: January 19, 2012

Dear Ms. Olivares:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113645

Indications for Use

510(k) Number (if known): K113645

Device Name: RegenerOss Allograft Putty Plus Mineralized

Indications For Use:

RegenerOss Allograft Putty Plus Mineralized is a bone filling material indicated for dental intraosseous and oral/maxillofacial defects including: localized ridge augmentations, extraction sockets, cystic defects, sinus lifts, peri-implant defects, defects associated with root resection or apicoectomy, and periodontal defects.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113645