



K080418

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Date: February 15, 2008

APR 30 2008

Submitted by: Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4326 Fax: 386-418-1627

Trade Names:

Regenafil®, Regenaform®, Altiva DBM Paste, Altiva DBM with cortical cancellous chips, BioSet™, BioSet™ IC, RTI Allograft Paste, RTI Allograft Paste IC, Osteofil®, Osteofil® ICM

Classification Name and Code:

bone grafting material, human source (21 CFR 872.3930, product code NUN)

Substantial Equivalence:

The proposed devices are substantially equivalent to GRAFTON PLUS® DBM Paste, GRAFTON® DBM, Accell Connexus, and DBX® Demineralized Bone Matrix in design, function and intended use, and substantially equivalent to RTI Allograft Paste and RTI Allograft Paste IC in design, function, materials and processing.

Description:

Regenafil®, Altiva DBM Paste, BioSet™, RTI Allograft Paste, and Osteofil® contain human demineralized freeze-dried bone allograft (DFDBA, also known as demineralized bone matrix, DBM) in an inert porcine gelatin carrier. Regenaform®, Altiva DBM with cortical cancellous chips, BioSet™ IC, RTI Allograft Paste IC, and Osteofil® ICM contain human DFDBA and human cortical-cancellous bone chips in an inert porcine gelatin carrier.

Indications for Use:

These products are intended to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral and cranio-/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including

- Periodontal defects;
- Alveolar ridge augmentation;
- Extraction sockets (ridge preservation, implant preparation/ placement);
- Maxillary sinus floor elevation;
- Craniofacial augmentation;
- Root resection, apicoectomy and cystectomy;
- Tumor resection.

One or more of the product formulations, depending upon specific anatomical location and physician and/or dentist preference, can be placed in the dental intraosseous defect site.



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Summary of Technological Characteristics:

These devices are composed of demineralized and non-demineralized allograft bone in a gelatin carrier matrix. Finished product from each lot is evaluated for osteoinductivity using the modified athymic nude rat assay.¹ These devices have the same technological characteristics (i.e., design, material, and chemical composition) as the respective predicate device as listed in the table below:

| Device Name | Predicate Name | Technological Characteristics Comparison |
|---|------------------------|--|
| Regenafil® Altiva DBM Paste BioSet™ RTI Allograft Paste Osteofil® | RTI Allograft Paste | Same technological characteristics (i.e., design, material, and chemical composition) as the predicate |
| Regenaform® Altiva DBM with cortical cancellous chips BioSet™ IC RTI Allograft Paste IC Osteofil® ICM | RTI Allograft Paste IC | Same technological characteristics (i.e., design, material, and chemical composition) as the predicate |

Performance Data Supporting Substantial Equivalence Determination:

The proposed products are equivalent to RTI Allograft Paste and RTI Allograft Paste IC, but have different specific clinical indications. Results from animal and clinical studies demonstrate that these products are safe and effective for use in dental bone void filling applications.

¹ Findings from an animal model are not necessarily predictive of human clinical results.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2008

Mr. Travis Arola
Regulatory Affairs Manager
Regeneration Technologies, Incorporated
11621 Research Circle
P.O. Box 2650
Alachua, Florida 32616-2650

Re: K080418

Trade/Device Name: Regenafil®, Regenaform®, Altiva DBM Paste, Altiva DBM with Cortical Cancellous Chips, BioSet™, BioSet™ IC, RTI Allograft Paste, RTI Allograft Paste IC, Osteofil®, Osteofil® ICM
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: February 15, 2008
Received: February 15 2008

Dear Mr. Arola:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1071

K080418

Indications for Use

510(k) Number (if known): _____

- Device Names:
- Regenafil®
 - Regenaform®
 - Altiva DBM Paste
 - Altiva DBM with cortical cancellous chips
 - BioSet™
 - BioSet™ IC
 - RTI Allograft Paste
 - RTI Allograft Paste IC
 - Osteofil®
 - Osteofil® ICM

Indications for Use:

These products are intended to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral and cranio-/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including

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- Maxillary sinus floor elevation;
- Craniofacial augmentation;
- Root resection, apicoectomy and cystectomy;
- Tumor resection.

One or more of the product formulations, depending upon specific anatomical location and physician and/or dentist preference, can be placed in the dental intraosseous defect site.

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)

Shirley Rouse

(Division Sign-Off)
 Division of Anesthesiology, General Hospital
 Infection Control, Dental Devices

510(k) Number: K080418