NOV 3 0 2005 K042707

XII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

September 29, 2004

1. Submission Applicant & Correspondent:

Name:	Osteotech, Inc.
Address:	51 James Way Eatontown, NJ 07724
Phone No.:	(732) 542-2800
Contact Person:	Chris Talbot

2. Name of Product:

Trade/Proprietary/Model Name:	GRAFTON PLUS® DBM Paste
Common or Usual Name:	Demineralized Bone Matrix Allograft
Classification Name:	Bone Grafting Material

3. Devices to Which New Product is Substantially Equivalent:

Grafton Plus DBM Paste is substantially equivalent, for the purpose of this 510(k), to the following predicate devices.

Trade/Proprietary/Model Name	Manufacturer	510(K) #
TBM Sponge	Biocoll Laboratories	K960267
PerioGlass-BioGlass Bone Graft Particulate	NovaBone Products, Inc.	K040278
Calcium Hydroxylapatite Implant	BioForm, Inc.	K030682
PerioGlass Plus-Settable Bone Graft Substitute	NovaBone Products, Inc.	K031073

In addition, GRAFTON PLUS® DBM Paste is substantially equivalent to human freeze dried bone, such as demineralized bone matrix, to which one or more predicate devices in this device category have claimed substantial equivalence.

4. Device Description:

GRAFTON PLUS® DBM Paste is a human bone allograft product consisting of human demineralized bone matrix (DBM) mixed with an inert starch-based additive. It is intended to fill and/or augment dental intraosseous, oral and cranio-/maxillofacial defects. GRAFTON PLUS® DBM Paste is provided in a ready-to-use paste-like, malleable form that can be molded or manipulated by the user into various shapes. It is provided in various package sizes by volume.

GRAFTON PLUS® DBM Paste is an osteoinductive bone graft product in that it forms ossicles of bone when implanted ectopically in an athymic rat model. It is produced using a process that has been validated to consistently produce osteoinductive DBM as measured in the athymic rat test model.

5. Intended Use/Indications
GRAFTON PLUS® DBM Paste is 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/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. GRAFTON PLUS® DBM Paste may be used alone in a manner comparable to autogenous bone chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either allograft or autograft bone or bone marrow as a bone graft extender. GRAFTON PLUS® DBM Paste is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. GRAFTON PLUS® DBM Paste is resorbed/remodeled and is replaced by host bone during the healing process.

6. Technical Comparison
GRAFTON PLUS® DBM Paste is substantially equivalent to one or more predicate devices with respect to materials in that it consists of human demineralized bone matrix and an inert non-tissue additive. It is provided in a ready-to-use paste-like, malleable form that can be molded or manipulated by the user into various shapes. It is implanted in this malleable state and does not set or harden prior to or after implantation.

7. Performance Data
Studies of bone formation with GRAFTON PLUS® DBM Paste were conducted using an animal model. These studies demonstrated consistent bone formation with GRAFTON PLUS® DBM Paste.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2005

Mr. Christopher Talbot
Director of Regulatory Affairs
Osteotech, Incorporated
51 James Way
Eatontown, New Jersey 07724

Re: K042707
Trade/Device Name: GRAFTON PLUS® DBM Paste
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: November 21, 2005
Received: November 22, 2005

Dear Mr. Talbot:

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

K042707

III. Indications for Use – Statement

510(k) Number (if known):_____

Device Name: GRAFTON PLUS® DBM Paste

Indications for Use:

GRAFTON PLUS® DBM Paste is 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/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. GRAFTON PLUS® DBM Paste may be used alone in a manner comparable to autogenous bone chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either allograft or autograft bone or bone marrow as a bone graft extender. GRAFTON PLUS® DBM Paste is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. GRAFTON PLUS® DBM Paste is absorbed/remodeled and replaced by host bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...fection Control, Dental Devices

...(k) Number: K042707

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)