JAN 3 2006

K051188

Attachment 3

XII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

December 16, 2005

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® DBM (Gel, Flex, Putty, Matrix, Crunch)
Common or Usual Name:	Demineralized Bone Matrix Allograft
Classification Name:	Bone Grafting Material

3. Devices to Which New Product is Substantially Equivalent:

GRAFTON® DBM is substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.

In addition, GRAFTON® DBM 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® DBM is a human bone allograft product containing human demineralized bone matrix (DBM) and an inert additive for intraoperative handling. It is intended to fill and/or augment dental intraosseous, oral and cranio-/maxillofacial defects. GRAFTON® DBM is provided ready-to-use in various physical forms. It is packaged in various sizes by volume or dimension for single patient use.

GRAFTON® DBM is a demineralized bone product that is osteoconductive as well as osteoinductive in an athymic rat assay. It is prepared via a proprietary processing method of Osteotech, Inc. that has been validated to consistently produce DBM that is osteoinductive in an athymic rat assay. Product and process consistency are confirmed via ongoing testing of GRAFTON® DBM finished product for osteoinductivity in this validated athymic rat assay utilizing a

five-point linear scale (0,1,2,3,4) to score bone formation at 28 days*. This bone forming activity exhibited by GRAFTON® DBM in this athymic rat surrogate assay should not be interpreted as a predictor of clinical performance.

*Edwards, J.T., PhD, Diegmann, M.H., MS, Scarborough, N.L., PhD.: Osteoinduction of Human Demineralized Bone: Characterization in a Rat Model. *Clinical Orthopaedics*, December, 1998, Volume 357.

5. Intended Use/Indications

GRAFTON® DBM 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® DBM 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® DBM is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. GRAFTON® DBM is resorbed/remodeled and is replaced by host bone during the healing process.

6. Technical Comparison

GRAFTON® DBM is substantially equivalent to one or more of the predicate devices with respect to materials in that it contains human demineralized bone matrix (DBM) in a resorbable non-tissue additive or carrier. It is provided ready-to-use in various malleable/flexible forms that can be molded, manipulated or cut by the user into various shapes or sizes. It is implanted in this malleable/flexible state.

7. Performance Data

The results of studies in animals and humans show that GRAFTON® DBM performs at least as well as, if not better than, predicate devices, autograft and/or demineralized bone matrix. Additional relevant animal and clinical data exist that support the successful performance of GRAFTON® DBM.

8. Viral Inactivation

GRAFTON® DBM is produced by a proprietary production process that has been validated to inactivate viruses including: HIV-1; hepatitis B virus (duck hepatitis virus as model); hepatitis C virus (bovine diarrhea virus as model), CMV; and Polio virus. This process is used to further reduce the risk of disease transmission via the use of this product beyond the protection provided by donor testing and screening procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 2006

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

Re: K051188
Trade/Device Name: GRAFTON® DBM
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: December 19, 2005
Received: December 20, 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

Enclosure

K051188

Attachment 4

III. Indications for Use – Statement

510(k) Number (if known): K051188

Device Name: GRAFTON® DBM

Indications for Use:

GRAFTON® DBM 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® DBM 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® DBM is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. GRAFTON® DBM is absorbed/remodeled and replaced by host bone during the healing process.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division of General Hospital, Infection Control, Dental Devices

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