

DEC 16 2005

K05 1195

## XII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

December 15, 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<sup>®</sup> DBM (Gel, Flex, Putty, Matrix, Crunch, Orthoblend)  
Common or Usual Name: Demineralized Bone Matrix Allograft  
Classification Name: Resorbable Bone Void Filler

### 3. Devices to Which New Product is Substantially Equivalent:

GRAFTON<sup>®</sup> 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.

### 4. Device Description:

GRAFTON<sup>®</sup> DBM is a human bone allograft product containing human demineralized bone matrix (DBM) and an inert additive for intraoperative handling. It is intended for use in filling bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure. GRAFTON<sup>®</sup> DBM is provided ready-to-use in various physical forms and in various package sizes by volume or dimension.

GRAFTON<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> DBM is intended for use as a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e., spine, pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. GRAFTON<sup>®</sup> DBM is resorbed/remodeled and is replaced by host bone during the healing process

## 6. Technical Comparison

GRAFTON<sup>®</sup> 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 showed that GRAFTON<sup>®</sup> DBM performs at least as well as, if not better than, predicate devices and/or autograft. Additional relevant animal and clinical data exist that support the successful performance of GRAFTON<sup>®</sup> DBM.

## 8. Viral Inactivation

The DBM in GRAFTON<sup>®</sup> 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.

The process used to produce the non-demineralized cancellous bone chips in Grafton<sup>®</sup> DBM Orthoblend does not afford the same degree of viral inactivation as the process used to produce the DBM. However, the risk of disease transmission with this tissue component remains low due to multiple safeguards that are rigorously employed, including donor screening, laboratory testing and material processing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 16 2005

Mr. Christopher Talbot  
Director, Regulatory Affairs  
Osteotech, Inc.  
51 James Way  
Eatontown, NJ 07724

Re: K051195  
GRAFTON ® DBM  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler devices  
Regulatory Class: Class II  
Product Code: MBP, MQV  
Dated: September 16, 2005  
Received: September 19, 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.

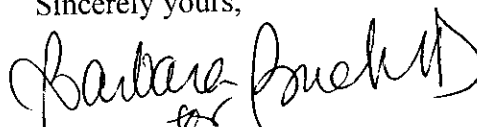
Page 2 – Mr. Christopher Talbot

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) 276-0120. 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,



Mark N. Melkerson.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

III. Indications for Use – Statement

510(k) Number (if known): K051195

Device Name: GRAFTON® DBM

Indications for Use:

GRAFTON® DBM is intended for use as a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e., spine, pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. GRAFTON® DBM is resorbed/remodeled and is replaced by host bone during the healing process.

Prescription Use X  
(Per 21 CFR 801.109)

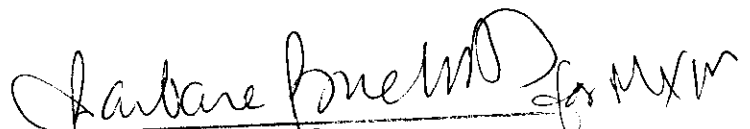
OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K051195