

September 5, 2008

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®II eDBM
 Common or Usual Name: Demineralized Bone Matrix Allograft
 Classification Name: Resorbable Bone Void Filler

3. Devices to Which New Product is Substantially Equivalent:

GRAFTON®II eDBM 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®II eDBM is a human bone allograft product containing human demineralized bone matrix (DBM) and surface demineralized cortical bone chips sealed in an absorbable mesh pouch 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®II eDBM is provided ready-to-use in various package sizes by volume or dimension and is intended for single patient use.

GRAFTON®II eDBM 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 shown to consistently produce DBM that is osteoinductive in an athymic rat assay. Product and process consistency are confirmed via ongoing testing of GRAFTON®II eDBM 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®II eDBM in the athymic rat surrogate assay should not be interpreted as a predictor of human 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.

K082615

5. Intended Use/Indications

GRAFTON®II eDBM is intended for use as a 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®II eDBM is resorbed/remodeled and is replaced by host bone during the healing process.

6. Technical Comparison

GRAFTON®II eDBM is substantially equivalent to one or more of the predicate devices with respect to materials in that it contains human demineralized bone matrix (DBM) and surface demineralized cortical bone chips. It is provided ready-to-use in various forms that can be manipulated by the user to contour the surgical site and may be secured to the graft site with sutures, staples or wires if the surgeon desires. GRAFTON®II eDBM is implanted in this malleable/flexible state and does not harden prior to or after implantation.

7. Performance Data

The results of *in vivo* studies in animals showed that GRAFTON®II eDBM 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 demineralized bone matrix in GRAFTON®II eDBM.

8. Viral Inactivation

GRAFTON®II eDBM fibers and chips are produced by proprietary processing steps that have been validated or shown 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. These processes are 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.



OCT 16 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteotech, Inc.
% Mr. Chris Talbot
Director, Regulatory Affairs
51 James Way
Eatontown, New Jersey 07724

Re: K082615
Trade/Device Name: GRAFTON® II eDBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 05, 2008
Received: September 09, 2008

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.

Page 2 – Mr. Chris Talbot

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

VI. Indications for Use – Statement

510(k) Number (if known): K082615

Device Name: GRAFTON® II eDBM

Indications for Use:

GRAFTON® II eDBM is intended for use as a 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® II eDBM is resorbed/ remodeled and is replaced by host bone during the healing process.

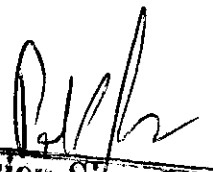
Prescription Use X
(Per 21 CFR 801.109)

OR

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

(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 General, Restorative,
and Neurological Devices**
510(k) Number K 082615