NOV 2 3 2005

K043048

XII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

November 17, 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 PLUS® DBM Paste
Common or Usual Name:	Demineralized Bone Matrix Allograft
Classification Name:	Resorbable Bone Void Filler

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) #
Exactech Resorbable Bone Paste	Exactech	K020078
Exactech Resorbable Room Temperature Bone Paste	Exactech	K040755
Allomatrix Putty	Wright Medical	K020895
Allomatrix Putty	Wright Medical	K041186

4. Device Description:

GRAFTON PLUS® DBM Paste is a human bone allograft product consisting of human demineralized bone matrix (DBM) to which an inert starch-based carrier has been added. 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 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 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 PLUS® DBM Paste 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 PLUS® DBM Paste 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 PLUS® DBM Paste 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 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 of the predicate devices with respect to materials in that it consists of human demineralized bone matrix (DBM) and an inert resorbable non-tissue additive or carrier. It is provided in a ready-to-use paste-like, malleable form that can be molded or manipulated by the user into various shapes.

7. Performance Data
   The results of bone formation studies in animals showed that GRAFTON PLUS® DBM Paste performed comparably to autograft. Additional relevant animal and clinical data exist that support the performance of GRAFTON PLUS® DBM Paste.

8. Viral Inactivation
   GRAFTON PLUS® DBM Paste 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

NOV 23 2005

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

Re: K043048
GRAFTON PLUS® DBM Paste
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MBP
Dated: November 10, 2005
Received: November 14, 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) 276-0120. 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,

for 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): K043048

Device Name: GRAFTON PLUS® DBM Paste

Indications for Use:

Grafton Plus® DBM Paste 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 Plus®** DBM Paste is resorbed/remodeled and is replaced by host bone during the healing process.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (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 K043048