MAR 17 2005

K040262

XI. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

PROPRIETARY NAME: DBX® Demineralized Bone Matrix Putty
DBX® Demineralized Bone Matrix Paste
DBX® Demineralized Bone Matrix Mix

COMMON NAME: Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)

PROPOSED REGULATORY CLASS: Class II

CLASSIFICATION IDENTIFICATION: 21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device

PRODUCT CODE: MQV

PANEL CODE: 87 – Orthopedic Devices

SPONSOR: Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 08837
732-661-0202

INDICATIONS FOR USE:

DBX® Demineralized Bone Matrix is intended for use as bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. DBX® Putty can be used to fill bone voids in the extremities, posterolateral spine, pelvis and cranium. DBX® Paste and Mix can be used to fill bone voids in the extremities and pelvis. It is indicated for use in the treatment of surgically-created osseous defects or osseous defects created from traumatic injury.

DEVICE DESCRIPTION:

DBX® is intended for single patient use only. DBX® Demineralized Bone Matrix is available in three forms: Paste, Putty and Mix. DBX® products are completely resorbable. DBX® Paste and Putty are composed of processed human cortical bone; the DBX® Mix is composed of processed human corticocancellous bone. The bone granules are mixed with sodium hyaluronate ("NaHA") in varying combinations to form the DBX® Putty, Paste and Mix. All versions of DBX® are available in five sizes.

OSTEOINDUCTIVE POTENTIAL:

DBX® is assayed *in vivo* for its osteoinductive potential. Standard testing performed in an athymic mouse model must prove positive for lot release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Kathleen M. Laffan, RAC
Regulatory Submission Specialist
Musculoskeletal Tissue Foundation
125 may Street
Edison, NJ 08837

Re: K040262
DBX® Demineralized Bone Matrix Putty, Paste, and Mix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV, GXP
Dated: December 22, 2004
Received: December 23, 2004

Dear Ms. Laffan:

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.

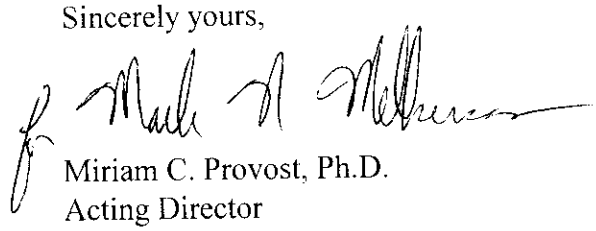
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040262

Device Name: DBX Demineralized Bone Matrix Putty, Paste and Mix

Indications for Use:

DBX® is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the:

Paste and Mix	Putty
extremities	extremities
pelvis	posterolateral spine
	pelvis
	cranium

It is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.

DBX® is for single patient use only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(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 K040262