JAN 13 2006

K042829

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

PROPRIETARY NAME: DBX® Strip

COMMON NAME: Bone void filler containing human demineralized bone matrix

PROPOSED REGULATORY CLASS: Class II

PRODUCT CODE: MQV

PANEL CODE: 87 – Orthopedic Devices

SPONSOR: Musculoskeletal Transplant Foundation

INDICATIONS FOR USE:

DBX Strip® is indicated as a bone void filler in the spine for the treatment of surgically created osseous voids or gaps that are not intrinsic to the stability of the bony structure. DBX Strip® is indicated for use in the posterior elements of the spine for posterolateral fusion only.

DBX Strip® is for single patient use only.

DEVICE DESCRIPTION:

DBX Strip® is a flat, malleable device composed of demineralized bone matrix ("DBM"), sodium hyaluronate ("NaHy"), sodium phosphate dibasic buffer and gelatin (porcine origin). DBX Strip® is for single patient use only and is available in five sizes.

SUBSTANTIAL EQUIVALENCE INFORMATION:

DBX Strip® was found to be substantially equivalent to the predicate devices. The safety and effectiveness is adequately supported by the substantial equivalence information and performance testing results provided within this Premarket Notification.

OSTEOINDUCTIVITY POTENTIAL:

DBX Strip® is osteoconductive and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final product will be tested to ensure the osteoinductive potential of the final product. It is unknown how the osteoinductive potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

VIRAL INACTIVATION:

A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses. The DBX Strip® process further reduces the risk of viral contamination beyond donor testing and screening procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Ms. Karen Hardwick
Manager, Regulatory Affairs
Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 08837

Re: K042829
DBX® Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: December 1, 2005
Received: December 2, 2005

Dear Ms. Hardwick:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042829

Device Name: DBX® Strip

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DBX Strip is for single patient use only.

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

(PLEASE NO 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 K042829