JUL 2 8 2005

K042125

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

PROPRIETRY NAME:	AFT
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
PROPOSED REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 CFR §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:

AFT is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the extremities and pelvis. It is indicated for treatment of surgically-created osseous defects or osseous defects created from traumatic injury. AFT is for single patient use only.

DEVICE DESCRIPTION:

AFT is composed of human demineralized bone matrix, human non-demineralized bone and sodium hyaluronate. All components of AFT are resorbable. AFT is aseptically processed and provided pre-loaded into a disposable delivery tube.

SUBSTANTIAL EQUIVALENCE INFORMATION:

AFT shares the same function and intended use and therefore is substantially equivalent to OSTEOSET® and Exactech Resorbable Bone Paste. In vivo testing in the athymic mouse model has demonstrated that AFT materials can effectively support new bone growth in osseous defects.

SAFETY AND EFFECTIVENESS INFORMATION:

Biocompatibility of AFT materials has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. AFT is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVITY POTENTIAL

AFT is osteoconductive, and has been shown to have osteoinductivity potential in an athymic mouse. Every lot of final product will be tested to ensure the osteoinductive potential of the final product. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION

The method for processing the DBM and CBM (cortical cancellous) contained in the AFT was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses. The CBM processing methods were determined to provide some viral inactivation potential for a wide range of viruses. In comparison, the CBM processing methods provided less viral inactivation potential than the DBM processing methods; therefore, the risk of disease transmission for the CBM component is greater than the DBM component. However, the risk for disease transmission for these components remains low due to the multiple safeguards employed, i.e., donor selection, laboratory testing, and material processing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2005

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

Re: K042125
AFT
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: May 31, 2005
Received: June 3, 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,

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

510(k) Number: K042125

Device Name: AFT

Indications for Use:

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AFT is intended for single patient use only.

Prescription Use__X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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 K042125