K110003

OCT 13 2011

VII. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

(Per 21 CFR 807.92)

General Company Information

Name: Musculoskeletal Transplant Foundation
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Date Prepared

December 23, 2010

General Device Information

Product Name: The MTF New Bone Void Filler

Classification: Bone Void Filler Containing Human Bone
21 CFR §888.3045 – Product code: MBP, MQV
Class II

Predicate Devices

DBX® Demineralized Bone Matrix
Musculoskeletal Transplant Foundation
510(k) K080399

DBX Strip®
Musculoskeletal Transplant Foundation
510(k) K042829, K062205

Osteoinductive Potential

The MTF New Bone Void Filler is osteoconductive and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final product is tested to ensure the osteoinductive potential of the final product. Standard testing performed in an athymic mouse model must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

Description

The MTF New Bone Void Filler is processed human bone that has been demineralized and combined with gelatin and sodium hyaluronate, which are naturally derived materials that are biocompatible and biodegradable. The sodium hyaluronate used in the manufacturing of the MTF New Bone Void Filler is not of animal origin. The MTF New Bone Void Filler comes in the form of a mixture of demineralized bone with gelatin and sodium hyaluronate, and a spatula that is necessary to mix the components. A hydrating agent can be used with the MTF New Bone Void Filler. Upon addition of a hydrating agent, the MTF New Bone Void Filler will achieve a flowable or moldable consistency. The resultant putty can then be manipulated by a surgeon into various shapes for ease and flexibility of use during surgical application.

Intended Use (Indications)

The MTF New Bone Void Filler is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. The MTF New Bone Void Filler is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. It is for use in the posterolateral spine only, for posterolateral spine fusions. The MTF New Bone Void Filler must be used in the spine with bone marrow aspirate.

The MTF New Bone Void Filler is for single patient use only.

Viral Clearance and 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 BVF process further reduces the risk of viral contamination beyond donor testing and screening procedures.

Substantial Equivalence

This submission supports the position that the MTF New Bone Void Filler is substantially equivalent to a number of previously cleared devices, including:

DBX® Demineralized Bone Matrix - Musculoskeletal Transplant Foundation [K080399]
DBX Strip® - Musculoskeletal Transplant Foundation [K042829, K062205]

When comparing the MTF New Bone Void Filler to its predicate devices, there are no new types of safety and effectiveness questions. The MTF New Bone Void Filler has been demonstrated to be substantially equivalent to its predicate devices in the study "New Generation DBX Putty (DBM Putty III) Tested in a Rabbit Model of Posterolateral Lumbar Fusion."

Safety and Effectiveness Information

The MTF New Bone Void Filler is single-donor processed. The MTF New Bone Void Filler is aseptically processed and passes USP <71> Sterility Tests. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1270 and Part 1271 Human Tissue Intended for Transplantation.

Conclusion

Musculoskeletal Transplant Foundation believes that the information provided in this 510(k) submission establishes that similar legally marketed devices have been used for the same clinical applications as the MTF New Bone Void Filler. The materials from which the MTF New Bone Void Filler is fabricated have an established history of use, and the device has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Nancy Joy
Musculoskeletal Transplant Foundation
125 May Street
Edison, New Jersey 08837

OCT 13 2011

Re: K110003
Trade/Device Name: MTF New Bone Void Filler (BVF)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: October 5, 2011
Received: October 6, 2011

Dear Ms. Joy:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

V. INDICATIONS FOR USE

510(k) Number (if known): K110003

Device Name: MTF New Bone Void Filler

Indications for Use:

The MTF New Bone Void Filler is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. The MTF New Bone Void Filler is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. It is for use in the posterolateral spine only, for posterolateral spine fusions. The MTF New Bone Void Filler must be used in the spine with bone marrow aspirate.

The MTF New Bone Void Filler is for single patient use only.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K110003