K090855

SEP 18 2009

5. 510(k) Summary

Submitter:
ETEX Corporation
38 Sidney Street
Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

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Date Prepared: September 10, 2009

Product Code(s): MBP (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Classification Name: Filler, Bone Void, Osteoinductive (21 CFR 888.3045)

Proprietary Name: EquivaBone Osteoinductive Bone Graft Substitute

Predicate Device(s):
CaP Plus (ETEX Corporation, K063050)
CaP Plus (ETEX Corporation, K080329)
EquivaBone Osteoinductive Bone Graft Substitute (ETEX Corporation, K090310)
Actifuse™ (ApaTech Limited, K082575)
Vitoss Bioactive Foam Bone Graft Substitute (Orthovita, K083033)

Device Description: EquivaBone is a biocompatible bone graft substitute material consisting of synthetic calcium phosphate, carboxymethyl cellulose (CMC) and human demineralized bone matrix (DBM). It is supplied in a single use kit as sterile powders and hydration solution that are mixed together at the time of use in the operating room to form flowable putty which is implanted manually or can be extruded through a syringe. After implantation the product hardens at body temperature and resorbs and remodels

during the healing process. Each lot of DBM contained within EquivaBone is assayed for osteoinductive potential in an athymic nude mouse model. This may or may not be predictive of EquivaBone osteoinductivity in humans.

Intended Use: EquivaBone is an osteoinductive bone graft substitute that is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis that are not intrinsic to the stability of the bony structure. These voids or gaps may result from natural occurring bone disease, traumatic injury or surgical intervention.

Materials: Synthetic calcium phosphate, carboxymethyl cellulose (CMC) and demineralized bone matrix (DBM)

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

ETEX Corporation
% Mr. Christopher Klaczyk
38 Sidney Street
Cambridge, Massachusetts 02139

Re: K090855
Trade/Device Name: EquivaBone Osteoinductive Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: September 10, 2009
Received: September 11, 2009

Dear Mr. Klaczyk:

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,

for

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

Enclosure

4. Indications For Use

510(k) Number (if known): K090855

Device Name: EquivaBone Osteoinductive Bone Graft Substitute

Indications for Use:

EquivaBone is an osteoinductive bone graft substitute that is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis that are not intrinsic to the stability of the bony structure. These voids or gaps may result from natural occurring bone disease, traumatic injury or surgical intervention.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K090855