K062630

ETEX Corporation Medical Device 510(k) Submission
OssiPro Bone Substitute Material
CONFIDENTIAL

JUN 28 2007

7. 510(k) SUMMARY AS REQUIRED UNDER 21 CFR 807.87(h)

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR:	ETEX Corporation University Park at MIT 38 Sydney Street, 3rd Floor Cambridge, MA 02139 Phone: (617) 577-7270 Fax: (617) 577-7170
510(k) CONTACT:	Frances A. Florence Regulatory Affairs Specialist
TRADE NAME:	OssiPro Bone Substitute Material
COMMON NAME:	Bone Void Filler Bone Graft Material Bone Substitute Material
CLASSIFICATION:	Class II
CLASSIFICATION NAME:	21 CFR 888.3045 Resorbable Calcium Salt Bone Void Filler Device
PRODUCT CODE:	MQV
PREDICATE DEVICE(S):	CaP_3 Bone Substitute Material, (K033138) α-BSM® Bone Substitute Material (K011048) JAX™ Granules Bone Void Filler (K010557)

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Device Description:
OssiPro Bone Substitute Material is an injectable synthetic, biocompatible bone graft substitute material. It is intended for use in bone void filler applications in the spine, pelvis, and extremities. At the time of use, OssiPro is combined with the hydration solution and is mixed to a smooth consistency. The material can be delivered to the defect site by injection with provided syringe or with desired needle/cannula (not provided). After delivering the paste to the treatment site, it forms pores while hardening at body temperature and converts to a macro-porous, poorly crystalline hydroxyapatite (PCHA) scaffold. The end product has a similar chemical identity and crystalline structure to that of natural bone. OssiPro Bone Substitute Material is an osteoconductive bone graft substitute that resorbs and is replaced with new bone over time.

Indications for Use:
OssiPro Bone Substitute Material is intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OssiPro is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Basis of Substantial Equivalence:
OssiPro Bone Substitute Material has the same intended use and similar technological characteristics CaP_3 Bone Substitute Material, α-BSM® Bone Substitute Material, and JAX™ Granules Bone Void Filler. Differences between OssiPro, CaP_3, α-BSM®, and JAX™ products do not raise any new questions of safety and effectiveness. Thus, the OssiPro Bone Substitute Material is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2007

ETEX Corporation
% Ms. Frances A. Florence
Regulatory Affairs Specialist
University Park at MIT
38 Sidney Street, 3rd Floor
Cambridge, Massachusetts 02139

Re: K062630
Trade Name: OssiPro Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class: II
Product Code: MQV
Dated: April 25, 2007
Received: April 26, 2007

Dear Ms. Florence:

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 toll-free number (800) 638-2041 or (240) 276-3150 or at the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for

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

Enclosure

510(k) Number (if known) K062630

Device Name: OssiPro Bone Substitute Material

Indications for Use:

OssiPro Bone Substitute Material is an injectable, self setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OssiPro is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

(Please Do Not Write Below This Line-Continue On Another Page As Needed)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062630

Prescription Use _____ OR Over-The Counter Use _____

(Per 21 CFR 801.109)