8. 510(k) SUMMARY AS REQUIRED UNDER 21 CFR 807.87(H) K080329

SUMMARY OF SAFETY AND EFFECTIVENESS

APR 28 2008

SPONSOR: ETEX Corporation
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510(k) CONTACT: Pamela W. Adams, RAC
Senior Vice President and Chief Operating Officer

TRADE NAME: CaP Plus
Equivabone
CaP/DBM

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, MBP

PREDICATE DEVICE(S): CaP Plus Bone Substitute Material (K063050)
CaP_3 Bone Substitute Material (K033138)
Optium DBM™ Gel & Putty (K053098)

Device Description:
CaP Plus is a biocompatible bone graft substitute material consisting of synthetic calcium phosphate, carboxymethyl cellulose (CMC) and human demineralized bone matrix (DBM). After implantation, the product hardens at body temperature; then resorbs and remodels during the healing process. Each lot of DBM supplied with CaP Plus is assayed for osteoinductive potential in an athymic nude mouse model. This may or may not be predictive of CaP Plus osteoinductivity in humans.

Indications for Use:
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. It is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Basis of Substantial Equivalence:
CaP Plus shares the same function and intended use as the predicate devices. CaP Plus was found to be substantially equivalent to the predicate devices. The safety and effectiveness of CaP Plus is adequately supported by the substantial equivalence data and test results provided with this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2008

ETEX Corporation
% Ms. Pamela W. Adams, RAC
Senior Vice President and Chief Operating Officer
University Park at MIT
38 Sidney Street, 3rd Floor
Cambridge, MA 02139

Re: K080329
Trade/Device Name: CaP Plus
Regulation Number: CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: January 31, 2008
Received: February 11, 2008

Dear Ms. Adams:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

ETEX Corporation Medical Device 510(k) Submission
CaP Plus

510(k) Number (if known) _____

Device Name: CaP Plus

Indications for Use:

CaP Plus 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. It is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Prescription Use **X** OR Over-The Counter Use _____

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation

Neil R. Ogden for MKM

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

510(k) Number K080329