

**ETEX Corporation Medical Device 510(k) Submission  
CaP Plus  
CONFIDENTIAL**

K063050

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

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**SPONSOR:**

ETEX Corporation  
University Park at MIT  
38 Sidney Street, 3<sup>rd</sup> Floor  
Cambridge, MA 02139  
Phone: (617) 577-7270  
Fax: (617) 577-7170

NOV 19 2007

**510(k) CONTACT:**

Pamela W. Adams, RAC  
Senior Vice President and Chief Operating Officer

**TRADE NAME:**

CaP Plus

**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<sub>3</sub> Bone Substitute Material (K033138)  
Optium DBM™ Gel & Putty (K053098)  
ALLOMATRIX® Putty (K020895)  
InterGro® DBM (K031399)

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**CaP Plus**  
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**Device Description:**

CaP Plus is a biocompatible bone graft substitute material consisting of synthetic calcium phosphate, an inert carrier, carboxymethyl cellulose (CMC) and human demineralized bone matrix (DBM). After implantation the product hardens at body temperature and resorbs and remodels during the healing process. Each lot of DBM contained within the 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 and 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 testing results provided within this premarket submission.



NOV 19 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

ETEX Corp  
% Ms. Pamala W. Adams  
Senior Vice President & Chief Operating Officer  
The Clark Bldg  
38 Sidney Street, 3<sup>rd</sup> Floor  
Cambridge, MA 02139

Re: K063050  
Trade/Device Name: CaP Plus  
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 17, 2007  
Received: September 24, 2007

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.

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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

510(k) Number (if known)     K063050    

Device Name: CaP Plus

**Indications for Use:**

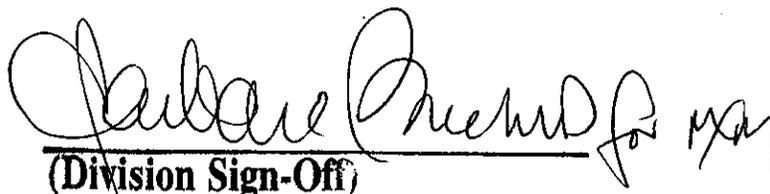
CaP Plus is intended for use in filling bone voids or defects of the skeletal system (such as the extremities and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. It is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use   X   OR Over-The Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number**     K063050