K071876

510(K) Summary of Safety and Effectiveness

DEC 17 2007

Cross.Bone

Submitted By:	TriMed, Inc. 25864 Tournament Road, Ste. A Valencia, CA 91355 (800)633-7221
Registration #:	2031009
Prepared By/Contact Person:	Kelli Anderson Phone: (661)312-7150 Fax: (661)254-8485
Proprietary Name:	Cross.Bone
Classification:	Class II: filler, bone void, calcium compound MQV - Section 888.3045
Summary Preparation Date:	October 26, 2007

I. Indications for Use:

Cross.Bone Blocks - CROSS.BONE BLOCK is recommended for bone reconstructive surgery or as a bone filler following loss of uninfected bone substance of artificial or degenerative origin, suitably reduced, fixed and stabilized where necessary.
- Filling losses of bone material resulting from a fracture.
- Filling losses of bone material after the resection of benign tumors or cysts

Cross.Bone Bottles - CROSS.BONE BOTTLE is recommended for bone reconstructive surgery or as a bone filler following loss of uninfected bone substance of artificial or degenerative origin, suitably reduced, fixed and stabilized where necessary.
- Filling losses of bone material resulting from a fracture.
- Filling losses of bone material after the resection of benign tumors or cysts.

Cross.Bone Syringe - CROSS.BONE SYRINGE is recommended for bone reconstructive surgery or as a bone filler following loss of uninfected bone substance of artificial or degenerative origin, suitably reduced, fixed and stabilized where necessary.
- Bone filler following a fracture,
- Bone filler following resection of benign tumors or cysts,

When the cavity to be filled is large, it is recommended to cover it with a resorbable membrane.

Cross.Bone Wedge - CROSS.BONE WEDGE is recommended for tibial osteotomy with internal fixation, and necessarily in combination with an osteosynthesis procedure (metallic plates and screws).

II. Device Description:

Cross.Bone is a resorbable, biphasic ceramic implant composed of 60% hydroxyapatite and 40% β-tricalcium phosphate in the form of granules. It is used as a bone filler and for bone reconstruction.

III. Substantial Equivalence:

K032268 – BIOMATLANTE, MBCP (Blocks)
K051774 – BIOMATLANTE, MBCP (Granules)
K060061 – Stryker Corp., Stryker Injectable Cement

Kelli Anderson
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2007

Trimed, Inc
% Ms. Kelli Anderson
Regulatory Affairs Specialist
25864 Tournament Rd, Suite A
Valencia CA 91355

Re: K071876
Trade/Device Name: Cross.Bone
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: December 1, 2007
Received: December 3, 2007

Dear Ms. Anderson:

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Indications for Use

510(k) Number (if known): Unknown

Device Name: Cross.Bone

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

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

510(k) Number K071872