APR 2 1 2005 K050357

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510(k) Summary for CAMCERAM TCP

1. SPONSOR

Name : CAM implants BV
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Date Prepared: February 2005

2. DEVICE NAME

Proprietary Name: CAMCERAM TCP

Common/Usual Name: Bone void filler

Classification Name: Bone void filler

3. PREDICATE DEVICES

Proprietary Name: Vitoss scaffold (OrthoVita), K994337

Proprietary Name: Conduit TCPgranules (Depuy Acromed), K014053

4. DEVICE DESCRIPTION

CAMCERAM TCP is a porous calcium phosphate resorbable bone void filler for the repair of bony defects. The product comprises of a beta-Tricalcium Phosphate and is 90% porous. The product is provided sterile available in granules 1-4 mm and a block form.

5. INTENDED USE

CAMCERAM TCP is a resorbable bone void filler intended to fill bony void or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The CAMCERAM TCP and the predicate devices are all similar in design, materials of construction and function. CAMCERAM TCP has been compared in physico-chemical testing with the predicate devices which confirmed the composition and resorption profile. The safety and biocompatibility testing performed for calcium phosphates and the long history of safe clinical use for tri-calcium phosphate products support the safe use of CAMCERAM TCP. CAMCERAM TCP meets the applicable requirements of the FDA guidance documents on bone void fillers.

7. TESTING

The CAMCERAM TCP is tested to conform to the recognized standard, ASTM F1088 "Standard Specification for Composition of Beta-Tricalcium Phosphate for suregical Implantation". The devices to which the CAMCERAM TCP claims substantial equivalence are the Vitoss scaffold (Orthovita) and Conduit TCP (Depuy Acromed) have been used safely for many years in the clinical environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

Mr. Rutger Kuipers
Manager QA/RA
CAM Implants BV
Zernikedreef 6
2333 CL Leiden
The Netherlands

Re: K050357
Trade/Device Name: CAMCERAM TCP Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 14, 2005
Received: February 14, 2005

Dear Mr. Kuipers:

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: CAMCERAM TCP Bone Void Filler

Indications for Use:

CAMCERAM TCP is a bone void filler is a resorbable implant intended to fill bony void or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

Prescription Use _X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 subpart D) (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 General, Restorative, and Neurological Devices

510(k) Number K050357