2 510(k) Summary [as required by 21 CFR 807.92(c)]

FEB 2 6 2003

Submitter's Name / Contact Person

Biomet, Inc.
56 East Bell Drive
Warsaw, IN 46581-0587

Contact
Mary Verstynen
Director of Clinical Affairs

General Information

Trade Name	Calcigen™ PSI bone graft substitute
Common Name	Bone graft substitute; bone void filler
Classification Name	Resorbable Calcium Salt Bone Void Filler

Equivalent Devices

Product	Manufacturer	510(k) #
Mastergraft Resorbable Ceramic	Medtronic Sofamor Danek, Inc.	K020986 K012506
chronOS Tricalcium Phosphate	Synthes	K013072
Calcium Phosphate Granular Bone Void Filler	Biomet, Inc.	K011531
Apatight HA-Bone Graft Substitute	Cerabio. LLC	K013960
Apatight-TCP Bone Graft Substitute	Cerabio, LLC	K013966
Cerasorb Ortho	Curasan Ag	K014156
Conduit TCP Granules	Depuy Acromed	K014053
BSM Bone Substitute Material	Depuy Orthopaedics, Inc.	K011048
Vitoss Scaffold Synthetic Cancellous Bone Void Filler	Orthovita Co.	K994337
Pro Osteon Implant 500R Resorbable Bone Graft Substitute	Interpore Cross Intl.	K990131

Device Description

Calcigen™ PSI bone graft substitute is a resorbable osteoconductive scaffold composed of 60% hydroxyapatite (HA) and 40% tri-calcium phosphate (TCP). The device is available as granules, cubes, or cylinders. Calcigen™ PSI is porous with multidirectional interconnected pores resembling that of cancellous bone. Calcigen™ PSI is supplied sterile for single patient, one time use only.

Intended Use

Calcigen™ PSI bone graft substitute is indicated for bony voids or gaps of the skeletal system (i.e., the extremities, spine 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 disease or traumatic injury to the bone. Calcigen™ PSI resorbs and is replaced with bone during the healing process.

Substantial Equivalence Comparison

Calcigen™ PSI is biocompatible because it is comprised of medical grade HA and TCP, which are known to be biocompatible with human bony tissue. Because of its substantial similarity in materials, structure, and porosity to several other FDA-cleared calcium phosphate bone graft substitutes, Calcigen™ PSI can be assumed to have appropriate physicochemical properties to create an adequate environment for bone ingrowth, permit device resorption, and result in adequate formation of bone. The submitted information demonstrated that Calcigen™ PSI bone graft substitute is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Ms. Mary L. Verstynen
Director of Clinical Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K030178
Calcigen™ PSI Bone Graft Substitute
Regulatory Class: Unclassified
Product Code: MQV
Dated: January 15, 2003
Received: January 17, 2003

Dear Ms. Verstynen:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030178

Device Name: Calcigen™ PSI bone graft substitute

Indications for Use:

Calcigen™ PSI bone graft substitute is indicated for bony voids or gaps of the skeletal system (i.e., the extremities, spine 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 disease or traumatic injury to the bone. Calcigen™ PSI resorbs and is replaced with bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K030178