JUN 11 2002

K013790

BIOMET

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
56 Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Telephone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: Calcigen™-S Bone Void Filler

Common Name: Calcium Sulfate Dihydrate

Classification Name: Filler, Calcium Sulfate (Unclassified)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Calcigen™-S Bone Void Filler is substantially equivalent to Wright Plaster of Paris Pellets (OsteoSet® Pellets) (K960978, K963562, K963587) and Wright Plaster of Paris Bone Void Filler Kit ($CaSo_4$ powder)(K963587) manufactured by Wright Medical Technology, Inc., Arlington, TN.

Device Description: Calcigen™-S Bone Void Filler is a bone filler that resorbs and is replaced with bone during the healing process. The product is available in two forms, paste and granuales.

Intended Use: Calcigen™-S Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from a traumatic injury to the bone. Calcigen™-S Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

Summary of Technologies: Similar to the predicate device, Calcigen™-S Bone Void Filler is a resorbable, radiopaque, osteoconductive, isothermic calcium sulfate based material intended for identical indications.

Non-Clinical Testing: Non-clinical testing included material properties such as set time, exothermic temperature, purity, porosity and mass/volume ratio. Biocompatability testing showed the material to be non-toxic, non-mutagenic, non-hemolytic, non-cytotoxic, and non-pyrogenic. Comparative testing with the predicate device showed equivalence in terms of dissolution rate, and surface pH. Animal testing demonstrated equivalence with the predicate in an *in vivo* situation both histologically and mechanically.

Clinical Testing: none provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2002

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O Box 587
Warsaw, Indiana 46581-0587

Re: Re: K013790
Trade Name: Calcigen-S Bone Void Filler
Regulatory Class: unclassified
Product Code: MQV
Dated: March 12, 2002
Received: March 14, 2002

Dear Ms. Beres:

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K013790

Device Name: Calcigen™-S Bone Void Filler

Indications For Use:

Calcigen™-S Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from a traumatic injury to the bone. Calcigen™-S Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

for Mark N Melkerson

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

510(k) Number K013790

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)