JUL 17 2003

510(k) Summary **ASpine USA Osteo-G Bone Void Filler System**

K031319

ADMINISTRATIVE INFORMATION

Manufacturer Name:	ASpine USA 3645 Grand Avenue, Suite 104 Oakland, CA 94610
Official Contact:	Gordon Tao President/CEO Telephone (510) 251-6798 FAX (510) 251-6262
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Filler, calcium sulfate preformed pellets
Trade/Proprietary Name:	Osteo-G Bone Void Filler System
Common Name:	bone void filler

DEVICE CLASSIFICATION

Calcium sulfate preformed pellets have not been classified by FDA. On January 13, 1998, the Orthopaedic and Rehabilitation Devices Panel recommended that the calcium sulfate bone void filler device be assigned to Class II, Special Controls, and a Proposed Rule classifying the Resorbable Calcium Salt Bone Void Filler Device to Class II was issued by FDA in the Federal Register of February 7, 2002 (67 FR 5753). The Product Code for the device is MQV.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Osteo-G Bone Void Filler System complies include American Society for Testing and Materials (ASTM) Standard F2224-03 *Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants*, U.S.P. 24 N.F.-19, and ANSI/AAMI/ISO 11137 *Sterilization of Health Care Products - Radiation Sterilization.*

INTENDED USE

The Osteo-G Bone Void Filler System, pellets or paste, are intended for filling of bony voids or gaps, i. e., of the extremities, spine or pelvis, that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets or paste provide a bone void filler that is bioabsorbable and is replaced with bone during the healing process. Osteo-G Bone Void Filler System pellets or paste may be used at an infected site.

DEVICE DESCRIPTION

The Osteo-G Bone Void Filler System is an osteoconductive, bioabsorbable, calcium sulfate dihydrate implant for use as a bone graft substitute or bone void filler. The system consists of prefabricated calcium sulfate dihydrate pellets or a kit for fabricating calcium sulfate dihydrate implants to custom shape and size or for *in situ* use. The device is radiopaque and is presterilized for single use.

The Osteo-G Bone Void Filler System pellets are provided in three sizes, each with cylindrical shape, as follows:

a) 5 mm diameter, 5 mm high
b) 5 mm diameter, 3 mm high
c) 3 mm diameter, 3 mm high

The Osteo-G Bone Void Filler System kit is provided in one size: a ten gram quantity of calcium sulfate hemihydrate powder component with a three milliliter mixing solution component. Once mixed, the powder and solution produce a moldable paste that can be custom shaped.

Material Composition

The Osteo-G Bone Void Filler System pellets are made of calcium sulfate dihydrate with stearic acid as a processing aid. The Osteo-G Bone Void Filler System kit consists of powdered calcium sulfate hemihydrate and a mixing solution of purified water, glycerin, methylcellulose, and hydroxyethylcellulose. All calcium sulfate components have a purity of not less then 98% calcium sulfate, exclusive of water, when measured by USP 24 NF-19 or methods derived therefrom, as specified by ASTM Standard F2224-03.

EQUIVALENCE TO MARKETED PRODUCT

Aspine USA submits the following information and exhibits to demonstrate that, for the purposes of FDA's regulation of medical devices, the Osteo-G Bone Void Filler System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices.

The design and functional characteristics of the Osteo-G Bone Void Filler System and the predicate devices are substantially the same. They function by filling voids or gaps in non-load-bearing osseous defects. The predicate devices include the Smith & Nephew JAX Granules Bone Void Filler (K010557) Wright Plaster of Paris Pellets (K963562), the Wright Plaster of Paris Bone Void Filler Kit (K963587), the Osteoset BVF Kit (K010532), the Interpore Cross Osteoplast Bone Void Filler (K991854), the Biocomposites Ltd. Stimulan Calcium Sulfate Bone Void Filler Kit (K003954), and the Biomet Orthopedics Calcigen-S Bone Void Filler (K013790). All of these devices are intended to fill osseous voids or gaps and consist of calcium sulfate.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

ASpine USA, Inc.
c/o Mr. Floyd G. Larson
President
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K031319
Trade Name: Osteo-G Bone Void Filler System
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: April 24, 2003
Received: April 25, 2003

Dear Mr. Larson:

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

Device Name: Osteo-G Bone Void Filler System

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Indications for Use:

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

510(k) Number K031319

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____