BIOMET K070015

510(k) Summary

Preparation Date: December 22, 2006 NOV 3 0 2007

Applicant/Sponsor: Biomet Manufacturing Corporation

Contact Person: Gary E. Baker

Proprietary Name: Cobalt™ V Radiopaque Vertebroplasty Bone Cement

Common Name: PMMA Bone Cement

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement (§ 888.3027)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Osteopal® V – Heraeus Kulzer GMBH (K050085)
Spineplex™ Radiopaque Bone Cement – Stryker (K032945)
Cobalt™ HV Bone Cement – Biomet Inc. (K051496)

Device Description: Cobalt™ V Radiopaque Vertebroplasty Bone Cement provides two separate, pre-measured sterilized components which when mixed form a radiopaque, rapidly setting bone cement.

Intended Use: Cobalt™ V Radiopaque Vertebroplasty Bone Cement is indicated for the fixation of pathological fractures of the vertebral body due to osteoporosis, benign lesions and malignant lesions using a vertebroplasty or kyphoplasty procedure.

Summary of Technologies: Cobalt™ V Radiopaque Vertebroplasty Bone Cement has the same indications for use and technology as the predicate devices. Cobalt™ V Radiopaque Vertebroplasty Bone Cement is made of the same components as the predicate Cobalt™ HV Bone Cement. The ratio of ingredients has been modified to meet specific customer needs for vertebroplasty and kyphoplasty applications.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2007

Biomet Manufacturing Corporation
%Gary E. Baker
Regulatory Specialist
PO Box 587
Warsaw, Indiana 46581

Re: K070015
Trade/Device Name: Cobalt™ V Radiopaque Vertebroplasty Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, NDN
Dated: October 30, 2007
Received: November 02, 2007

Dear Mr. Baker:

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

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):_____

Device Name: Cobalt™ V Radiopaque Vertebroplasty Bone Cement

Indications For Use:

Cobalt™ V Radiopaque Vertebroplasty Bone Cement is indicated for the fixation of pathological fractures of the vertebral body due to osteoporosis, benign lesions and malignant lesions using a vertebroplasty or kyphoplasty procedure.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (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)

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

510(k) Number K070015