K051496

AUG 4 - 2005

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510(k) Summary

Cobalt™ HV Bone Cement

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lonnie Witham
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: Cobalt™ HV Bone Cement

Common Name: Bone Cement

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Device: Palacos® R Bone Cement
Approved by: PMA (P810020, S001, S002, S003, S004) reclassified into Class II
Manufacturer: Biomet Inc.; 56 East Bell Drive; Warsaw, IN 46582

Predicate Device: Generation 4® Bone Cement
Cleared by: 510(k) Notification (K993836)
Manufacturer: Biomet Inc.; 56 East Bell Drive; Warsaw, IN 46582
(Relevant to packaging and sterilization processes cleared for this device)

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

Materials used:
40 g powder component (copolymer):

- Methylmethacrylate-methylacrylate copolymer containing FD&C Blue No. 2 Aluminum Lake
- Benzoyl peroxide, hydrous 75%
- Zirconium dioxide

20 ml of liquid component (monomer):

- Methylmethacrylate (stabilized with hydroquinone)
- N,N-dimethyl-p-toluidine

Methymethacrylate monomer is the primary constituent of the liquid component. In much smaller quantities are the accelerator, N, N-dimethyl-p-toluidine, and the stabilizer, hydroquinone, both are typical constituents of PMMA bone cement.

When the powder and liquid components are mixed, the accelerator speeds the generation of free radicals and the stabilizer in the liquid reacts with many of the early free radicals, but is soon consumed. Free radicals can then initiate formation of polymer chains.

Polymerization proceeds slowly over the first few minutes. Polymer chains at the surface of the powder beads mingle with monomer and newly formed polymer chains, while smaller beads may dissolve completely. The cement temperature rises as set time of the cement approaches. Polymerization is essentially complete and the bone cement is hard within 15 minutes.

Intended Use / Indications for Use:
Cobalt™ Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, sickle cell anemia osteoporosis, secondary severe joint destruction following trauma or other conditions (also for fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures.

Summary of the Technological Characteristics:
Extensive in-vitro testing was performed in accordance with *Class II Special Controls Guidance: Polymethylmethacrylate (PMMA) Bone Cement: Guidance for Industry & FDA-July 17, 2002* to demonstrate the equivalence of Cobalt™ Bone Cement to Palacos® R Bone Cement. Test results showed that the technological characteristics (mechanical, chemical, physical & handling properties) of the two cements are substantially the same.

Non-Clinical:
The substantial equivalence of Cobalt™ Bone Cement to Palacos® R Bone Cement was determined by performing comparative in vitro testing and then comparing the results. The results showed that Cobalt™ Bone Cement possesses mechanical, chemical, physical and handling characteristics necessary to fulfill its intended use. In summary, Cobalt™ Bone Cement is substantially equivalent to Palacos® R Bone Cement for its primary intended use of fixation of prosthetic components as described in the device labeling. No clinical testing was performed.

Clinical Testing: No clinical testing was required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2005

Mr. Lonnie Witham
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 6581-0587

Re: K051496
Trade/Device Name: Cobalt™ HV Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: June 3, 2005
Received: June 6, 2005

Dear Mr. Witham:

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,

for Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K051496

Device Name: Cobalt™ HV Bone Cement

Indications for Use:

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Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-96)

(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 K051496