K061144

JUN - 8 2006

SECTION 5:
510(k) SUMMARY

Trade Name: DePuy CMW 2 Gentamicin Bone Cement
DePuy CMW 3 Gentamicin Bone Cement

Common Name: Antibiotic bone cement

Classification Name: Bone cement, antibiotic (21 CFR 888.3027, Product Code MBB)

Contact Person:
Natalie S. Heck
Manager, Regulatory Affairs
DePuy Orthopaedics Inc.

Tel.: (574) 267-8143
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Equivalent to: DePuy CMW 1 Gentamicin Bone Cement (K053002)

SmartSet GMV Endurance Gentamicin Bone Cement (K041656).

SmartSet GHV Gentamicin Bone Cement (K033563).

DePuy CMW 2 Bone Cement (K053003)

DePuy CMW 3 Bone Cement (K053003)

Device Description: DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement are self-curing, polymethylmethacrylate (PMMA) bone cements containing the antibiotic gentamicin (at the rate of 1g active gentamicin in 40g of PMMA bone cement powder), for seating and securing of a metal or plastic prosthesis to living bone.

Intended Use: DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement are both indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Substantial Equivalence: DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement have the same intended use as DePuy CMW 1 Gentamicin Bone Cement, SmartSet GHV Gentamicin Bone Cement and SmartSet GMV Endurance Gentamcin Bone Cement.

DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement are composed of the same materials as DePuy CMW 1 Gentamicin Bone Cement, but the ratios of the individual components have been modified to produce cements with subtly different setting characteristics to meet user needs for differing surgical situations. DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement are similar in design and performance characteristics to DePuy CMW 1 Gentamicin Bone Cement, SmartSet GMV Endurance Gentamicin Bone Cement, SmartSet GHV Gentamicin Bone Cement, DePuy CMW 2 Bone Cement and DePuy CMW 3 Bone Cement; and similar in sterilization and packaging to DePuy CMW 1 Gentamicin Bone Cement, SmartSet GMV Endurance Gentamicin Bone Cement, DePuy CMW 2 Bone Cement and DePuy CMW 3 Bone Cement. The determination of substantial equivalence of DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement to these bone cements was based on a comparison of device technological characteristics and comparative product testing data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2006

DePuy Orthopaedics, Inc.
c/o Ms. Natalie Heck
Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46580

Re: K061144
Trade/Device Name: DePuy CMW 2 Gentamicin Bone Cement, DePuy CMW 3 Gentamicin Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: MBB
Dated: April 24, 2006
Received: April 25, 2006

Dear Ms. Heck:

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.

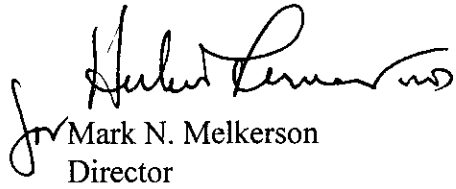
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K061144

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:	DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement
Indications for Use:	Use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

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

510(k) Number K061144

Prescription Use X AND/ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)