NOV 2 2 2005

K053002

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT:

Natalie S. Heck
Manager, Regulatory Affairs

TRADE NAME:

DePuy CMW 1 Gentamicin Bone Cement

COMMON NAME:

Polymethyl Methacrylate (PMMA) Bone Cement with Antibiotic.

CLASSIFICATION:

Class II; 21 CFR 888.3027

DEVICE PRODUCT CODE:

MBB

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy 1 Gentamicin Bone Cement (K041656)
(now branded DePuy CMW 1 Gentamicin Bone Cement).

SmartSet GMV Endurance Gentamicin Bone Cement (K033382).

SmartSet MV Endurance Bone cement (P960001/S1)
(previously branded Endurance Bone Cement)

DEVICE DESCRIPTION:

DePuy 1 Gentamicin Bone Cement is a self-curing cement. The cement allows the seating and securing of a metal or plastic prosthesis to living bone. The following modifications are being made:

- DePuy CMW 1 Gentamicin will be made available in a 20 gram presentation in addition to the previously cleared 40 gram presentation.
- Changes are being made to the formulation of the bone cement liquid component.

INTENDED USE AND INDICATIONS:

DePuy CMW 1 Gentamicin Bone Cement is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on similarities in formulations, manufacturing methods and intended use, DePuy believes that DePuy CMW 1 Gentamicin Bone Cement is substantially equivalent to the previously cleared and approved bone cements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2005

Natalie Heck
Manager, Regulatory Affairs
Depuy Orthopaedics, Inc
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K053002
Trade/Device Name: Depuy CMW 1 Gentamicin Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: MBB
Dated: October 24, 2005
Received: October 27, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications Statement

510(k) Number (if known):

Device Name: DePuy CMW 1 Gentamicin Bone Cement

Indications for Use:

DePuy CMW 1 Gentamicin Bone Cement is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Prescription Use ✓ OR/AND Over-The Counter Use
(Part 21 CFR 801.Subpart D) (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)

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

510(k) Number K053002