JAN 6 2006

K053445

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF SPONSOR:

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

MANUFACTURER:

DePuy International Ltd
Trading As DePuy CMW
Cornford Road
Blackpool, Lancashire
FY4 4QQ, England

510(k) CONTACT:

Natalie S. Heck
DePuy Orthopaedics, Inc.
Manager, Regulatory Affairs
Tel.: (574) 372-7469
Fax: (574) 371-4978
Email: nheck@dpyus.jnj.com

TRADE NAME:

SmartMix Cemvac Pre-filled with SmartSet HV Bone Cement
SmartMix Cemvac Pre-filled with SmartSet GHV Gentamicin Bone Cement

COMMON NAME:

PMMA Bone Cement

CLASSIFICATION:

PMMA Bone Cement:
Class II per 21 CFR 888.3027

Cement Mixer for Clinical Use:
Class I Exempt per CFR 888.4210

Cement Dispenser:
Class I Exempt per 21 CFR 888.4200

DEVICE CODES:

LOD, MBB, KIH, JDZ

SUBSTANTIALLY EQUIVALENT DEVICES:

SmartSet HV Bone Cement:
K023012

SmartSet GHV Gentamicin Bone Cement:
K033563

SmartMix Pre-filled Mixing System
K042591

Cemvac Ultra Pre-packed with DePuy 1 Bone Cement
K021499

DEVICE DESCRIPTIONS AND INDICATIONS:

SmartMix Cemvac is a vacuum mixing and syringe delivery system pre-packed with bone cement powder and liquid. The device is available in a single 60g or 80g unit. This submission adds SmartMix Cemvac pre-filled with SmartSet HV Bone Cement and SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement to the SmartMix Cemvac line.

SmartSet HV Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

SmartSet GHV 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 FOR SUBSTANTIAL EQUIVLENCE:

Based on the similarities of design, materials, intended use and testing results, SmartMix Cemvac pre-filled with SmartSet HV Bone Cement and SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement are substantially equivalent to the same bone cements, packaged in traditional bone cement packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Ms. Natalie S. Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K053445
Trade/Device Name: SmartMix Cemvac Pre-filled with SmartSet HV Bone Cement
SmartMix Cemvac Pre-filled with SmartSet GHV Gentamicin Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: PMMA Bone Cement
Regulatory Class: II
Product Code: LOD, MBB, KIH, JDZ
Dated: December 8, 2005
Received: December 12, 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.

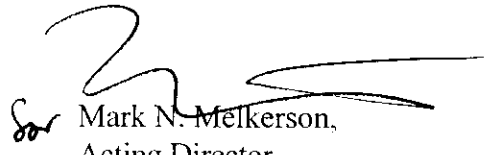
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 FOR USE STATEMENT

510(k) Number (if known): _____

Device Name:

SmartMix Cemvac Pre-filled with SmartSet HV Bone Cement

Indications for Use:

SmartSet HV Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

Device Name:

SmartMix Cemvac Pre-filled with SmartSet GHV Gentamicin Bone Cement

Indications for Use:

SmartSet GHV 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: X Part 21 CFR 801 Subpart D	AND/OR	Over-The-Counter Use: __ 21 CFR 807 Subpart C

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

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for MNM

Division of General, Restorative, and Neurological Devices

510(k) Number K053445