OCT 2 2 2004

K042591

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:
Tiffani Rogers
DePuy Orthopaedics, Inc
Regulatory Affairs Associate
Tel: (574) 371-4927 Fax: (574) 371-4978
E-mail: trogers1@dpyus.jnj.com

TRADE NAME:
SmartMix Pre-filled Mixing System

COMMON NAME:
Pre-filled Bone Cement Mixer for Clinical Use
Pre-filled Bone Cement Dispenser

CLASSIFICATION:
Cement Mixer for Clinical Use: Class I Exempt per CFR 888.4210
Cement Dispenser: Class I Exempt per 21 CFR 888.4200
PMMA Bone Cement: Class II per 21 CFR 888.3027

DEVICE CODE:
KIH pre-filled with LOD
JDZ pre-filled with LOD

SUBSTANTIALLY EQUIVALENT DEVICES:
Endurance Bone Cement: P960001 Supplement 1
SmartSet GMV Endurance Gentamicin Bone Cement: K033382 and K041656
Cemvac Ultra pre-packed with DePuy 1 Bone Cement: K021499

DEVICE DESCRIPTIONS AND INDICATIONS:

SmartMix Cemvac

SmartMix Cemvac is a vacuum mixing and syringe delivery system pre-packed with bone cement powder and liquid. The device is for single use only and reduces exposure to monomer fumes and cement porosity during preparation and avoids handling of bone cement during cement delivery. The device is available in a single 60g or 100g unit. Each unit pack consists of the following:

- A syringe barrel assembly pre-packed with bone cement powder.
- A monomer cartridge pre-loaded with two ampoules of bone cement liquid.
- Accessories consisting of a disposable mixing stand, a vacuum hose with filter attached, a vacuum tube adaptor and a central mixing rod.

SmartMix Bowl

SmartMix Bowl is a vacuum mixing system pre-packed with bone cement powder and liquid. The device is for single us only and reduces exposure to monomer fumes and cement porosity during preparation. The device is available in single 80g units. Each unit pack consists of the following:

- A bowl base pre-packed with bone cement powder.
- A monomer cartridge pre-loaded with two ampoules of bone cement liquid.
- Accessories consisting of a bowl lid with vacuum hose and filter attached, a vacuum tube adaptor and a spatula.

SmartSet MV Endurance Bone Cement

SmartSet MV Endurance Bone Cement is indicated for the fixation of prostheses to living bone in orthopedic 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 GMV Endurance Gentamicin Bone Cement

SmartSet GMV Endurance 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 EQUIVALENCE:

With the exception of the primary packaging of the powder component when pre-packed in SmartMix Cemvac or SmartMix Bowl, the bone cement formulations and indications for use are identical to their equivalent standard pack bone cements cleared by the FDA as follows:

- SmartSet MV Endurance Bone Cement listed as a note to file in February 2004 (a re-brand of the Endurance Bone Cement initially cleared by the FDA under P960001 Supplement 1 on 12th November 1997). Labeling was amended to reflect the re-branded cement. The formulation, specifications and indications of the bone cement remain the same.

- SmartSet GMV Endurance Gentamicin Bone Cement was initially cleared under K033382 on 5th February 2004 and later under K041656 on 1st July 2004 when the Gentamicin particle size was change from micronised to non-micronised.

Based on the similarities of design, materials, intended use and testing, the following devices are substantially equivalent to FDA cleared devices currently on the market.

- SmartMix Cemvac + SmartSet MV Endurance Bone Cement
- SmartMix Bowl + SmartSet MV Endurance Bone Cement
- SmartMix Cemvac + SmartSet GMV Endurance Gentamicin Bone Cement
- SmartMix Bowl + SmartSet GMV Endurance Gentamicin Bone Cement

On testing, the pre-packed bone cements have been found to be stable on storage in both systems and when mixed in SmartMix Cemvac and SmartMix Bowl, the physicomechanical properties and elution profile (for the medicated bone cement) have shown to be equivalent to mixing by the conventional bowl and spatula technique.

The materials used in the primary packaging of the powder component for both SmartMix Cemvac and SmartMix Bowl are the same as those used in Cemvac Ultra pre-packed with DePuy 1 Bone Cement (cleared by FDA under K021499 on 24th July 2002). The materials that come into contact with the powder and liquid components have been found to be compatible in their use application.

Predicate devices include SmartSet MV Endurance Bone Cement, SmartSet GMV Endurance Gentamicin Bone Cement and Cemvac Ultra pre-packed with DePuy 1 Bone Cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

Ms. Tiffani Rogers
Regulatory Affairs Associate
Depuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581

Re: K042591
Trade/Device Name: SmartMix Pre-Filled Mixing System
Regulation Number: 21 CFR 888.4210, 21 CFR 888.4200 and 21 CFR 888.3027
Regulation Name: Cement mixer for clinical use, Cement dispenser, Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: KIH, JDZ, LOD and MBB
Dated: September 21, 2004
Received: September 23, 2004

Dear Ms. Rogers:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, PhD, MD
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: SmartMix Pre-filled System

Indications for Use:

Device Name (unmedicated pre-filled systems):

SmartMix Cemvac + SmartSet MV Endurance Bone Cement
SmartMix Bowl + SmartSet MV Endurance Bone Cement

Indications:

SmartSet MV Endurance 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 (medicated pre-filled systems):

SmartMix Cemvac + SmartSet GMV Endurance Gentamicin Bone Cement
SmartMix Bowl + SmartSet GMV Endurance Gentamicin Bone Cement

Indications:

SmartSet GMV Endurance 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 ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for _____

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

510(k) Number K042591

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