K041656

JUL 0 1 2004

DePuy

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:	Tiffani Rogers Regulatory Affairs Associate
TRADE NAME:	DePuy 1 Gentamicin Bone Cement SmartSet GMV Endurance Gentamicin Bone Cement.
COMMON NAME:	Polymethyl Methacrylate (PMMA) bone cement with Antibiotic. Polymethyl Methacrylate (PMMA) and styrene co-polymer bone cement with Antibiotic.
CLASSIFICATION:	Class II; 21 CFR 888.3027
DEVICE PRODUCT CODE:	LOD
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy 1 Gentamicin Bone Cement (K023103), SmartSet GMV Endurance Gentamicin Bone Cement (K033382) and SmartSet GHV Gentamicin Bone Cement (K033563).

DEVICE DESCRIPTION:
DePuy 1 Gentamicin and SmartSet GMV Endurance Gentamicin Bone Cements are self-curing cements, containing one gram of Gentamicin in 40 grams PMMA (Polymethyl methacrylate, and Polymethyl methacrylate and styrene co-polymer). The cements allow the seating and securing of a metal or plastic prosthesis to living bone.

INTENDED USE AND INDICATIONS:
DePuy 1 Gentamicin and SmartSet GMV Endurance Gentamicin Bone Cements are 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:
The DePuy 1 Gentamicin and SmartSet GMV Endurance Gentamicin Bone Cements have the same basic design and the same intended use as the originally cleared bone cements. The Gentamicin Sulphate used in the cements is to be changed from micronised particles to non-micronised particles. Based on similarities in design, material, manufacturing method and intended use, DePuy believes that the DePuy 1 Gentamicin and SmartSet GMV Endurance Gentamicin manufactured with non-micronised are substantially equivalent to the previously cleared antibiotic bone cements manufactured with micronised Gentamicin. Lek Pharmaceutical and Chemical Company d.d are to remain the supplier of the active ingredient Gentamicin Sulphate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 0 1 2004

Re: K041656
Trade/Device Name: DePuy 1 Gentamicin and SmartSet GMV Endurance Gentamicin Bone Cements
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD, MBB
Dated: June 17, 2004
Received: June 18, 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 Miriam C. Provost

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: DePuy 1 Gentamicin and SmartSet GMV Endurance Gentamicin Bone Cements

Indications for Use:

DePuy 1 Gentamicin Bone Cement and SmartSet GMV Endurance Gentamicin Bone Cement are 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)

Page 1 of 1
(Posted November 13, 2003)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041656