K081163

MAY 14 2008

510(k) Summary

Date Prepared:	23 April 2008
510(k) Sponsor:	DePuy Orthopaedics, Inc 700 Orthopaedic Drive Warsaw, Indiana 46581 – 0988
Establishment Registration No:	1818910
Contact Person:	Suzana Otaño Project Manager, Regulatory Affairs Telephone: 305-269-6386 Fax: 305-269-6441 Email: sotano@dpyus.jnj.com
Trade Name of Device:	SmartSet GMV Gentamicin Bone Cement
Common Name:	Antibiotic bone cement
Classification Name:	Bone cement, antibiotic (21 CFR 888.3027, Product Code MBB and LOD)
Equivalent to:	SmartSet GMV Endurance Gentamicin Bone Cement (K041656) SmartSet GHV Gentamicin Bone Cement (K033563)
Device Description:	SmartSet GMV Gentamicin Bone Cement is a self-curing, radiopaque, polymethylmethacrylate based cement, containing the antibiotic gentamicin sulfate. The bone cement is used for securing a metal or polymeric prosthesis to living bone in arthroplasty procedures.
Intended Use:	SmartSet GMV 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.
Technological Characteristics:	The technological characteristics of the SmartSet GMV Gentamicin Bone Cement are equivalent to the predicate devices.

Substantial Equivalence:	The indications, intended use, formulation and finished product specifications of the SmartSet GMV Gentamicin Bone Cement are equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

DePuy Orthopaedics, Inc.
% Ms. Suzana Otano
Project Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, IN 46581-0988

Re: K081163
Trade/Device Name: SmartSet GMV Gentamicin Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD, MBB
Dated: April 23, 2008
Received: April 24, 2008

Dear Ms. Otano:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Indications for Use Statement

510(k) Number: _____

Device Name: SmartSet GMV Gentamicin Bone Cement

Indications For Use:

SmartSet GMV 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 AND/OR Over-the-Counter____

(Per 21 CFR 801 Subpart D) (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)

Neil RP Ogden for mxm

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

Page 1 of 1

510(k) Number K081163