K033563

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510(k) Summary
SmartSet GHV Gentamicin Bone Cement

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Tiffani D. Rogers
Regulatory Affairs Associate
(574) 371-4927

B. Device Information:

Proprietary Name:	SmartSet GHV Gentamicin Bone Cement
Common Name:	Methyl Methacrylate/Methyl Acrylate Copolymer bone cement with Antibiotic
Regulatory Class and Classification Name:	Class II Bone Cement, Antibiotic
Product Code:	LOD

C. 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.

D Device Description:

SmartSet GHV Gentamicin Bone Cement is a self-curing cement, to which one gram of (active) gentamicin is included in 40 grams of bone cement powder and 0.5 gram of (active) gentamicin is included in 20 grams of bone cement powder, for allowing the seating and securing of a metal or plastic prosthesis to living bone.

E. Substantial Equivalence:

The substantial equivalence of SmartSet GHV Gentamicin Bone Cement is demonstrated by its similarity in design, materials, sterilization and packaging to SmartSet HV Bone Cement (K023012) and its similarity in indications for use to DePuy 1 Gentamicin (K023103) and Simplex P with Tobramycin (K014199) Bone Cements.

The determination of substantial equivalence for this device was based on a detailed device description, product testing and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

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

Re: K033563
Trade/Device Name: SmartSet GHV Gentamicin Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD and MBB
Dated: November 10, 2003
Received: November 12, 2003

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) 594-4639. 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 may be obtained 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K033563

Device Name 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 Yes
(Per 21 CFR §801.109)

OR

Over-the-Counter Use No

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milkerson

General, Restorative
and Neurological Devices

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