K071927

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SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Spine, Inc. 325 Paramount Drive Raynham MA 02767-0350
510(k) CONTACT:	Sharon Starowicz Director of Regulatory Affairs
TRADE NAME:	Vertebroplastic™ Radiopaque Bone Cement
COMMON NAME:	Polymethyl Methacrylate (PMMA) Bone Cement
CLASSIFICATION:	Class II; 21 CFR 888.3027
DEVICE PRODUCT CODE:	NDN
SUBSTANTIALLY EQUIVALENT DEVICES:	Vertebroplastic™ Radiopaque Bone Cement (K043406) SmartSet GMV Endurance Gentamicin Bone Cement (K033382).

NOV 2 1 2007

DEVICE DESCRIPTION:

Vertebroplastic™ Radiopaque Bone Cement is a self-curing, radiopaque, polymethylmethacrylate (PMMA) cement, for filling of spinal vertebral body defects resulting from compression fracture, in order to provide stabilization of the collapsed vertebral body and pain relief. The following modifications are being made:

Change to the formulation of the bone cement liquid component.

INTENDED USE AND INDICATIONS:

Vertebroplastic™ Radiopaque Bone Cement is indicated for the treatment, using vertebroplasty or kyphoplasty procedures, of pathological fractures of the vertebral body caused by osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of modified Vertebroplastic™ Radiopaque Bone Cement to the identified predicate devices is demonstrated by its similarity in terms of technological characteristics (chemical composition, material properties, performance characteristics, manufacture, packaging and sterilization) to the Vertebroplastic ™ Radiopaque Bone Cement (K043406) and SmartSet GMV Endurance Gentamicin Bone Cement (K033382); and by its similarity in terms of intended use and indications for use to the Vertebroplastic ™ Radiopaque Bone Cement (K043406).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Depuy Spine, Inc.
% Ms. Sharon Starowicz
Director of Regulatory Affairs
325 Paramount Drive
Raynham, MA 02767-0350

Re: K071927
Trade/Device Name: Vertebroplastic™ Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Names: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, LOD
Dated: November 1, 2007
Received: November 2, 2007

Dear Ms. Starowicz:

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

000005

Indications for Use Statement

510(k) Number (if known):

Device Name: Vertebroplastic™ Radiopaque Bone Cement

Indications for Use:

The Vertebroplastic™ Radiopaque Bone Cement is indicated for the treatment, using vertebroplasty or kyphoplasty procedures, of pathological fractures of the vertebral body caused by osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X___ OR Over-The Counter Use
(Part 21 CFR 801.Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

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

510(k) Number K071927