**PREMARKET NOTIFICATION [510(k)] SUMMARY**

**Trade Name:** Vertebralplastic™ Radiopaque Bone Cement  
**Common Name:** Polymethylmethacrylate (PMMA) bone cement  
**Classification Name:** Filler bone cement (for vertebroplasty)  
**Regulatory Class:** Class II, per 21 CFR §888.3027,  
**Device Code:** NDN  
**510k Sponsor:** DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767-0350

**Manufacturer:** DePuy International Limited, trading as DePuy CMW  
Cornford Road  
Blackpool  
Lancashire FY4 4QQ  
United Kingdom

**Contact Person:** Sharon Starowicz,  
Director of Regulatory Affairs  
DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767-0350  
Tel.: (508) 828-2867; Fax: (508) 828-3797

**Equivalent to:**  
- KyphX® HV-R™ Bone Cement Model C01A (K041584)  
- Stryker SpinePlex™ Radiopaque Bone Cement (K032945)  
- Stryker Howmedica Surgical Simplex® P Radiopaque pre-packed in ACM and MixEvac II (K002652)  
- Cranioplastictm, acrylic cranioplasty material (K873689)

**Device Description:** Vertebralplastic™ Radiopaque Bone Cement is a self-curing, radiopaque, polymethylmethacrylate (PMMA) cement, for filling of spinal vertebral body defects, in order to provide stabilization of the vertebral body and pain relief. Vertebralplastic™ Radiopaque Bone Cement has a low viscosity and long working and setting time.
Ms. Sharon Starowicz  
Director of Regulatory Affairs  
DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767-0350

Re: K043406  
Trade Name: Vertebroplastic Radiopaque Bone Cement  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Bone Cement for Vertebroplasty  
Regulatory Class: III  
Product Code: NDN  
Dated: June 8, 2005  
Received: June 9, 2005

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html>.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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: Vertebroplastic™ Radiopaque Bone Cement

Indications for Use:

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 AND/OR Over-The-Counter Use
(Part 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)