K093828

AUG 12 2010

**PREMARKET 510(k) SUMMARY**

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| Summary Date: | August 2010 |
| Trade Name: | KyphX HV-R® Bone Cement |
| Common Name: | PMMA Bone Cement |
| Classification Name: | Bone Cement (21 CFR part 888.3027) |
| Device Code, Class: | NDN, Class II |
| Manufacturer's Name:<br>Address: | Medtronic Spine LLC<br>1221 Crossman Avenue Sunnyvale, CA 94089<br>Establishment Registration No. 2953769 |
| Contact Person: | Mary Rose Sr. Principal Regulatory Affairs Specialist<br>1221 Crossman Avenue Sunnyvale, CA 94089<br>Telephone: 408-548-5203<br>Fax: 408-548-6501 |
| Performance Standards: | The requirements of the Food Drug and Cosmetic Act, under section 514 for performance standards, are not applicable to the KyphX HV-R® Bone Cement. |
| Predicate Devices: | K041584 KyphX HV- R® Bone Cement<br>K033801 KyphX HV-R® Bone Cement |
| Intended Use: | KyphX HV-R® Bone Cement is indicated for the treatment of pathological fractures of the verteral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. |

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| Device Description: | KyphX HV-R® Bone Cement is provided as a two-component system. The powder component consists of a PMMA copolymer (polymethyl methacrylate/methyl-methacrylate-styrene-copolymer) with barium sulfate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer, with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter. The powder and liquid components are mixed prior to use. |
| Sterilization: | KyphX HV-R® Bone Cement is provided sterile. KyphX HV-R® Bone Cement is intended for single-use only. |
| Substantial Equivalence: | Testing was conducted to verify the KyphX HV-R® Bone Cement performance for in vivo applications in support of the labeling changes. Handling properties (dough times) were assessed on multiple lots of bone cement, including lots that were manufactured at the extremes of the Setting Time specification range. The dough time and hardening time were also measured at various ambient temperatures using bone filler devices, the intended mode of clinical application.<br><br>The results of this testing support the determination of substantial equivalence. Therefore, it is concluded that the modified KyphX HV-R Bone Cement is substantially equivalent to the predicate KyphX HV-R Bone Cement. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 12 2010

Medtronic Spine LLC
% Ms. Mary Rose
Sr. Principal Regulatory
Affairs Specialist
1221 Crossman Avenue
Sunnyvale, California 94089

Re: K093828
Trade/Device Name: KyphX HV-R® Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: July 28, 2010
Received: July 30, 2010

Dear Ms. Rose:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

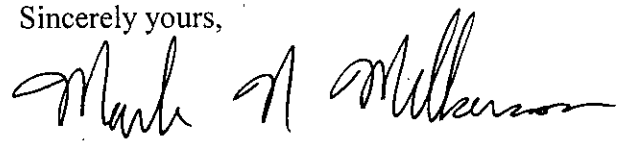
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AUG - 1 2 - 2010

# INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: KyphX HV-R® Bone Cement

**Indications for Use**:

KyphX HV-R® Bone Cement is indicated for the treatment of pathological fractures of the verteral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093828