



Food and Drug Administration  
10903 New Hampshire Avenue  
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April 28, 2015

Medtronic Sofamor Danek USA, Incorporated  
Ms. Kathy L. Remsen  
Senior Regulatory Affairs Program Manager  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: K150460

Trade/Device Name: KYPHON<sup>®</sup> HV-R<sup>®</sup> Bone Cement  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) bone cement  
Regulatory Class: Class II  
Product Code: NDN  
Dated: March 10, 2015  
Received: March 13, 2015

Dear Ms. Remsen:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**INDICATIONS FOR USE**

**510(k) Number (if known):** K150460

**Device Name:** KYPHON® HV-R® Bone Cement

**Indications for Use:**

KYPHON® HV-R® Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a kyphoplasty or vertebroplasty 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                        AND/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)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**KYPHON® HV-R® Bone Cement  
510(k) Summary**

**February 2015**

**Company:** Medtronic Sofamor Danek USA, Inc.  
1800 Pyramid Place  
Memphis, Tennessee 38132  
Telephone: (901) 396-3133  
Fax: (901) 346-9738

**Contact:** Kathy L. Remsen  
Senior Regulatory Affairs Program Manager

**Proprietary Trade Name:** KYPHON® HV-R® Bone Cement

**Common Name:** Bone Cement

**Classification Name:** Cement, bone, vertebroplasty

**Product Code:** NDN

**Regulation:** 21 CFR 888.3027

**Classification:** II

**Description:** KYPHON® HV-R® Bone Cement is provided as a two component system. The powder component consists of a PMMA copolymer (polymethylmethacrylate/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.

**Indications for Use:** KYPHON® HV-R® Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer or benign lesions using a kyphoplasty or vertebroplasty 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.

**Summary of the Technological Characteristics:** The subject KYPHON® HV-R® Bone Cement has the same fundamental scientific technology as the predicates KYPHON® HV-R® Bone Cement (K093828 S.E. 8/12/2010) and KYPHON® Xpede™ Bone

Cement (K102397 S.E. 2/28/2011). The subject device utilizes equivalent implant materials and sterilization methods.

**Identification of Legally Marketed Devices:** The subject KYPHON® HV-R® Bone Cement is substantially equivalent to the KYPHON® HV-R® Bone Cement (K093828 S.E. 8/12/2010) and KYPHON® Xpede™ Bone Cement (K102397 S.E. 2/28/2011).

**Conclusion:** The design features, device materials, chemical composition, device performance, packaging of the device materials, manufacturing and sterilization methods are substantially equivalent to the previously cleared KYPHON® HV-R® Bone Cement (K093828 S.E. 8/12/2010) and KYPHON® Xpede™ Bone Cement (K102397 S.E. 2/28/2011). The updated indication does not raise new issues of safety or effectiveness. The intended use for KYPHON® HV-R® Bone Cement has not changed and is identical to the predicates KYPHON® HV-R® Bone Cement (K093828 S.E. 8/12/2010) and KYPHON® Xpede™ Bone Cement (K102397 S.E. 2/28/2011).