



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Pamela Edwards
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

August 24, 2016

Re: K160983

Trade/Device Name: KYPHON[®] HV-R[®] Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: August 1, 2016
Received: August 2, 2016

Dear Ms. Edwards:

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 Parts 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K160983

Device Name
Kyphon® HV-R® Bone Cement

Indications for Use (Describe)

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 cementoplasty (i.e. 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. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) Summary
Medtronic Sofamor Danek**

KYPHON® HV-R® Bone Cement

August 2016

Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact	Pamela Edwards Principal Regulatory Affairs Specialist Direct Telephone: 901-399-2125
Date Prepared	March 2016
Common Name	KYPHON® HV-R® Bone Cement
Regulatory Class Regulation Number Regulation Name and Device Product Classification Code	Class II 21 CFR 888.3027 Polymethylmethacrylate (PMMA) bone cement NDN
Predicate Devices	<u>KYPHON® HV-R® Bone Cement</u> K150460, S.E. 04/28/2015 (Primary Predicate) <u>KYPHON® Xpede™ Bone Cement</u> K151227, S.E. 11/16/2015 The predicate devices have not been subject to a design related recall.
Description of Device	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 cementoplasty (i.e. 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. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Comparison of Technological Characteristics with the Predicate Devices	The subject KYPHON® HV-R® Bone Cement has the same fundamental scientific technology as the predicates KYPHON® HV-R® Bone Cement (K150460 S.E. 4/28/2015) and KYPHON® Xpede™ Bone Cement (K151227 S.E. 11/16/2015). The subject device utilizes equivalent implant materials, sterilization methods and bacterial endotoxin testing applying the same 20 EU/mL pyrogen limit specifications utilizing the gel clot test method as the predicates KYPHON® HV-R® Bone Cement (K150460 S.E. 4/28/2015) and KYPHON® Xpede™ Bone Cement (K151227 S.E. 11/16/2015).
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 (K150460 S.E. 4/28/2015) and KYPHON® Xpede™ Bone Cement (K151227 S.E. 11/16/2015). 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 (K150460 S.E. 4/28/2015) and KYPHON® Xpede™ Bone Cement (K151227 S.E. 11/16/2015).