DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 6, 2016

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K152604
Trade/Device Name: KYPHON HV-R® Fenestrated Screw Cement, CD HORIZON® Fenestrated Screw Set
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, MNI
Dated: December 8, 2015
Received: December 9, 2015

Dear Mr. Grant:

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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K152604

Device Name
KYPHON HV-R® Fenestrated Screw Cement

Indications for Use *(Describe)*
When used in conjunction with the CD HORIZON® Fenestrated Screws, KYPHON HV-R® Fenestrated Screw Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. KYPHON HV-R® Fenestrated Screw Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K152604

Device Name
CD HORIZON® Fenestrated Screw Set

Indications for Use *(Describe)*
When used in conjunction with KYPHON HV-R® Fenestrated Screw Cement, the CD HORIZON® Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD HORIZON® Fenestrated Screws augmented with KYPHON HV-R® Fenestrated Screw Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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)

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510(k) Summary – K152604

Medtronic Sofamor Danek USA, Inc.

December 2015

Submitter	Medtronic Sofamor Danek USA , Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact(s)	Lee Grant Distinguished Regulatory Affairs Advisor Direct Telephone – 901-344-0807 Pamela Edwards Principal Regulatory Affairs Specialist Direct Telephone -901-399-2125
Date Prepared	December 30, 2015
Trade Name	1) KYPHON HV-R® Fenestrated Screw Cement 2) CD HORIZON® Fenestrated Screw Set
Regulatory Class **Regulation Number** **Regulation Name and Device Product Classification Code**	1) KYPHON HV-R® Fenestrated Screw Cement Class II 888.3027 Polymethylmethacrylate (PMMA) Bone Cement PML 2) CD HORIZON® Fenestrated Screw Set Class II 21 CFR 888.3070 Pedicle Screw System MNI
Predicate Devices	**1)** KYPHON® HV-R® Bone Cement (Primary Predicate**)** K150460 KYPHON® HV-R® Bone Cement (SE 04/28/15) 2) CD HORIZON® Spinal System K042025 CD HORIZON® Spinal System (SE 08/25/04) and K113174 CD HORIZON® Spinal System (SE 11/21/11) The predicate devices have not been subject to a design related recall
Description of Device	1) KYPHON HV-R® Fenestrated Screw Cement is self-curing PMMA based (high viscosity, radiopaque) bone cement. KYPHON HV-R® Fenestrated Screw Cement will be provided sterile in two components: 20 grams of powder and nine grams of liquid. The powder contains methylmethacrylate-styrene co-polymer, barium sulfate as a radiopacifier, and di-benzoyl peroxide as an initiator. This liquid contains methylmethacrylate monomer, N, N dimethyl-p-toluidine as a promoter and hydroquinone as a stabilizer. The powder and liquid

	components are mixed, in the provided liquid-to-powder proportions, into a homogenous paste, to initiate the polymerization reaction of monomer into polymer. 2) The CD HORIZON® Fenestrated Screw Set consists of a variety of cannulated multi-axial screws (MAS) with fenestrations offered in diameters ranging from 4.5mm to 10.5mm, with lengths ranging from 30-100mm based on CD HORIZON® LEGACY™ and CD HORIZON® SOLERA™ implants contained in the CD HORIZON® Spinal System. The CD HORIZON® Fenestrated Screws are specifically designed to connect to 4.75mm, 5.5mm, and 6.0mm diameter rods and associated connecting components contained within the CD HORIZON® Spinal System. The screws contain six fenestrations near the distal tip of the screw which provides a controlled means to deliver a small amount of polymethylmethacrylate (PMMA) bone cement into a targeted vertebral body. These screws are provided non-sterile.
Indications for Use:	1) KYPHON HV-R® Fenestrated Screw Cement: When used in conjunction with the CD HORIZON® Fenestrated Screws, KYPHON HV-R® Fenestrated Screw Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. KYPHON HV-R® Fenestrated Screw Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised. **2)** CD HORIZON® Fenestrated Screw Set: When used in conjunction with KYPHON® HV-R Fenestrated Screw Cement, the CD HORIZON® Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD HORIZON® Fenestrated Screws augmented with KYPHON HV-R® Fenestrated Screw Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.
Comparison of Technological Characteristics with the Predicate Devices	1) The KYPHON® HV-R® Fenestrated Screw Cement is identical in composition, method of manufacture and sterilization to the primary predicate Kyphon® H-VR® Bone Cement cleared by the FDA in K150460 (SE 04/28/15). The predicate cement is intended to be used in patients diagnosed with pathological fractures in the vertebral body caused by conditions such as osteoporosis and cancer. The subject cement is also intended to be used in patients with metastatic cancer. Pathological fractures reflect one means in which spinal instability occurs and therefore in both instances the predicate and subject cement are intended to treat spinal instability. The only differences between the subject and predicate cement are the method in which the cement is delivered and that the subject cement is limited to patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of

	fusion. **2)** The screws which comprise the CD HORIZON® Fenestrated Screw Set have the same or similar indications, intended use, fundamental scientific technology, and are manufactured from similar materials as the pedicle screws found in the following FDA cleared CD HORIZON® Spinal System applications: K042025 (SE 08/25/2004) and K113174 (SE 11/21/2011). The predicate screws in this application are cleared for pedicle fixation in patients with spinal instability caused by tumors. The subject pedicle screws are also intended to provide pedicle fixation in patients diagnosed with spinal instability caused by tumors. Both the predicate and subject screws are cannulated, are manufactured from the same material, are similar in design, sizes and are intended to be used with the same spinal rods and connecting components. The primary difference is the subject screws contain fenestrations which allow PMMA cement to flow in a controlled manner through the screw and into the targeted pedicle.
Performance Data	Clinical data and Non-Clinical testing were provided in support of substantial equivalence of the subject device.
Conclusion	Based on the provided performance data, the subject KYPHON® HV-R Fenestrated Screw Cement is substantially equivalent to the KYPHON® HV-R® Bone Cement (K150460, SE 04/28/15) and the CD HORIZON® Fenestrated Screw Set is substantially equivalent to the CD HORIZON® Spinal System (K042025 (SE 08/25/2004) and K113174 (SE 11/21/2011)).