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

October 23, 2017

Re: K171938
Trade/Device Name: KYPHON™ Xpede™ Bone 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, NDN, MNI
Dated: September 14, 2017
Received: September 19, 2017

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 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 (DICE) 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 (DICE) 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

# Indications for Use

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

510(k) Number *(if known)*
K171938

Device Name
CD HORIZON™ Fenestrated Screw Set

Indications for Use *(Describe)*
When used without cement, the CD HORIZON™ Fenestrated Screws (with or without SEXTANT™ or LONGITUDE™ instrumentation) are intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, tumor and/or trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.

When used in conjunction with Medtronic HV-R™ Fenestrated Screw Bone Cement or Kyphon™ XPEDE™ Bone 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 either Medtronic HV-R™ Fenestrated Screw Bone Cement or Kyphon™ XPEDE™ Bone 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)

**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)*
K171938

Device Name
KYPHON™ Xpede™ Bone Cement

Indications for Use *(Describe)*
KYPHON™ Xpede™ 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. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. 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. Pathological fracture may include a symptomatic microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

When used in conjunction with CD HORIZON™ Fenestrated Screws, KYPHON™ Xpede™ bone 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. CD HORIZON™ Fenestrated Screws augmented with KYPHON™ Xpede™ Bone 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 – K171938**
**Medtronic Sofamor Danek**
**CD HORIZON™ Fenestrated Screw Set**
**October 20, 2017**

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| **Submitter** | Medtronic Sofamor Danek USA<br>1800 Pyramid Place<br>Memphis, Tennessee 38132<br>Telephone: (901) 396-3133<br>Fax: (901) 346-9738 |
| **Contact(s)** | Lee Grant<br>Distinguished Regulatory Affairs Advisor<br>Direct Telephone – 901-344-0807 |
| **Date Prepared** | October 20, 2017 |
| **Trade Name** | 1) Kyphon® Xpede™ Bone Cement<br>2) Medtronic HV-R™ Fenestrated Screw Cement (K152604)<br>3) CD HORIZON™ Fenestrated Screw Set |
| **Regulatory Class**<br>**Regulation Number**<br>**Regulation Name and Device Product Classification Code** | 1) Kyphon® Xpede™ Bone Cement and Medtronic HV-R™ Fenestrated Screw Cement<br>Class II<br>888.3027 Polymethylmethacrylate (PMMA) Bone Cement<br>PML, NDN<br>2) CD HORIZON™ Fenestrated Screw Set<br>Class II<br>21 CFR 888.3070 Pedicle Screw System<br>MNI |
| **Predicate Devices** | 1) K102397 - Kyphon® Xpede™ Bone Cement (Primary Predicate, SE 02/28/2011**)**<br>**Secondary Predicate**<br>2) K152604 – Kyphon HV-R™ Fenestrated Screw Cement (Medtronic HV-R™ Fenestrated Screw Cement) and CD HORIZON™ Fenestrated Screw Set (SE 01/06/16)<br>The predicate devices have not been subject to a design related recall |
| **Description of Device** | Kyphon Xpede™ Bone Cement is self-curing PMMA based (high viscosity, radiopaque) bone cement. Kyphon Xpede™ Bone Cement is 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.<br><br>Medtronic HV-R™ Fenestrated Screw Cement is self-curing PMMA based (high viscosity, radiopaque) bone cement. Medtronic HV-R™ Fenestrated Screw Cement is 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, |

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| | to initiate the polymerization reaction of monomer into polymer.<br>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 implants may also serve as traditional pedicle screws when used without bone cement. These screws are provided non-sterile. |
| **Indications for Use:** | When used without cement, the CD HORIZON™ Fenestrated Screws (with or without SEXTANT™ or LONGITUDE™ instrumentation) are intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, tumor and/or trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.<br><br>When used in conjunction with Medtronic HV-R™ Fenestrated Screw Bone Cement or Kyphon XPEDE™ Bone 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 Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ XPEDE™ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.<br><br>Additionally, KYPHON™ Xpede™ 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. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. 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. Pathological fracture may include a symptomatic 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** | 1) The Kyphon Xpede™ Bone Cement is identical in composition, method of manufacture and sterilization to the primary predicate Kyphon Xpede™ Bone Cement cleared by the FDA in K102397 (SE 02/28/11). 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 |

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| | 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.<br><br>**2)** No changes or additions have been made to the fenestrated screws which comprise the CD HORIZON™ Fenestrated Screw Set cleared previously in K152604 for the same indications when used in conjunction with cement augmentation. They are identical in all aspects with respect to indications, design, size, intended use, cannulation, fundamental scientific technology, and materials. |
| **Performance Data** | **Biocompatibility**<br>Identical to the primary predicate screws, the CD HORIZON™ Fenestrated Screws are provided non-sterile form. They are manufactured from medical grade titanium alloy (in accordance with ASTM F136), medical grade titanium (in accordance with ASTM F67) and medical grade cobalt-chromium-molybdenum alloy (in accordance with ASTM F1537).<br><br>The subject Xpede™ Bone Cement is identical to the predicate Xpede™ Bone Cement. The subject cement 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 predicate Kyphon Xpede™ Bone Cement (K102397).<br><br>The materials used in the implants and instruments have a long clinical history of safe and effective use in similar commercially available medical devices. Therefore, no additional biocompatibility testing is required.<br><br>**Mechanical Testing**<br>In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. Axial Pull Out Testing in accordance with ASTM F543-07 was performed and compared CD HORIZON™ Fenestrated Screws augmented with the subject Kyphon Xepede™ Bone Cement and the Medtronic HV-R™ Fenestrated Screw Cement. Test results demonstrated the pull-out strength of the screws were equivalent when using Kyphon Xpede™ Bone Cement or Medtronic HV-R™ Fenestrated Screw Cement.<br>Additionally, a flow rate analysis was performed to compare Kyphon Xpede™ Bone Cement to the Medtronic HV-R™ Fenestrated Screw Cement with respect to injection and flow characteristics of the two cements. The cements were evaluated using fluoroscopic imaging. Testing found the flow rates of the subject and predicate cements to be substantially equivalent. |
| **Conclusion** | Based upon the test results and additional supporting documentation provided in the pre-market notification, the subject Kyphon Xpede™ Bone Cement is substantially equivalent to the Kyphon® Xpede Bone Cement (K102397, SE 02/28/11) and to the Medtronic HV-R™ Fenestrated Screw Cement (K152604, SE 01/06/16). |