September 12, 2019

Medtronic Sofamor Danek, USA Inc.
Ms. Shweta Sharma
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K191148
Trade/Device Name: Medtronic HV-R™ Bone Cement, 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, NKB, NDN
Dated: April 29, 2019
Received: April 30, 2019

Dear Ms. Sharma:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191148

Device Name
CD Horizon™ Fenestrated Screw Set

Indications for Use *(Describe)*

When used without cement, 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 (DDD - 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 Cement or Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic, lumbar, or sacral 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.

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.

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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:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191148

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 in patients with advanced stage tumors involving the thoracic, lumbar, or sacral 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191148

Device Name
Medtronic HV-R™ Fenestrated Screw Cement

Indications for Use *(Describe)*

When used in conjunction with CD Horizon™ Fenestrated Screws, Medtronic 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 in patients with advanced stage tumors involving the thoracic, lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Medtronic 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)

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510(k) SUMMARY

August 21, 2019

I. Company: Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone Number: (901) 396-3133

Contact: Shweta Sharma
Principal Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: shweta.s.sharma@medtronic.com

Proprietary Trade Name:	Kyphon™ Xpede™ Bone Cement Medtronic HV-R™ Fenestrated Screw Cement CD Horizon™ Fenestrated Screw Set
Common Name:	Bone Screw, Pedicle Screw, Cement
Classification Name/ Regulation Numbers/ Classification/ Classification Product Code/ Subsequent Product Codes (if any)	PML, NDN Kyphon™ Xpede™ Bone Cement and Medtronic HV-R™ Fenestrated Screw Cement Polymethylmethacrylate (PMMA) bone cement 888.3027 Class II NKB CD Horizon™ Fenestrated Screw Set Thoracolumbosacral pedicle screw system 888.3070 Class II

II. Predicate Devices:

Primary Predicate:
Medtronic HV-R™ Bone Cement (K152604, S.E. 01/06/2016)

Additional Predicates:
CD Horizon™ Spinal System (K170679, S.E. 05/11/2017)

CD Horizon™ Fenestrated Screw Set (K171938, S.E. 10/23/2017)

CD Horizon™ Fenestrated Screw Set (K170347, S.E. 04/04/2017)

Kyphon™ HV-R™ Bone Cement (K180700, S.E. 05/18/2018)

Kyphon™ Xpede™ Bone Cement (K163032, S.E. 02/27/2017)

These predicate devices have not been subject to a design-related recall.

III. Device Description:

CD Horizon™ Fenestrated Screw Set

The CD Horizon™ Fenestrated Screw Set consists of a variety of cannulated screws. These screws contain a series of fenestrations which allows polymethylmethacrylate (PMMA) bone cement (Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement) to be injected into the treated site. This cement is used to augment screw fixation into the pedicle in patients whose life expectancy is of insufficient duration to permit achievement of fusion. These implants may also serve as traditional pedicle screws when used without bone cement in patients with non-compromised bone quality.

CD Horizon™ Fenestrated Screws are specifically designed to connect to appropriate rods and associated connecting components contained within the CD Horizon™ Spinal System. Refer to the CD Horizon™ Spinal System package insert for information regarding those implants. Care should be taken so the correct components are used in the spinal construct.

CD Horizon™ Fenestrated Screw Set implant components are fabricated from medical grade titanium and/or medical grade titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy. Never use stainless steel and titanium implant components in the same construct.

To achieve best results, do not use CD Horizon™ Fenestrated Screw implants with components from any system other than the CD Horizon™ Spinal System. As with all orthopedic and neurosurgical implants, CD Horizon™ Fenestrated Screw implants should never be reused under any circumstances.

Kyphon™ Xpede™ Bone Cement

Kyphon™ Xpede™ Bone Cement is a polymethylmethacrylate (PMMA) that contains approximately 30% barium sulfate. It is designed for delivery in a highly viscous state. 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 and benzoyl peroxide. The liquid contains methylmethacrylate (monomer), hydroquinone and N, N dimethyl-p-toluidine.

Medtronic HV-R™ Fenestrated Screw Cement

Medtronic HV-R™ Fenestrated Screw Cement is a polymethylmethacrylate (PMMA) that contains approximately 30% barium sulfate. It is designed for delivery in a highly viscous state. 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, and benzoyl peroxide. The liquid contains methylmethacrylate (monomer), hydroquinone and N, N dimethyl-p-toluidine.

IV. Indications for Use:

CD Horizon™ Fenestrated Screw Set

When used without cement, CD Horizon™ Fenestrated Screws (with or without Sextant™ or Longitute™ instrumentation) are intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - 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 Cement or Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic, lumbar, and sacral 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.

Kyphon™ Xpede™ Bone Cement

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, or sacral 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.

Medtronic HV-R™ Fenestrated Screw Cement

When used in conjunction with CD Horizon™ Fenestrated Screws, Medtronic 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 in patients with advanced stage tumors involving the thoracic, and lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Medtronic HV-R™ Fenestrated Screw Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

V. Comparison of the Technological Characteristics with the Predicate Device:

The primary predicate for the subject devices is CD Horizon™ Fenestrated Screw Set (K171938, S.E. 10/23/2017). The subject CD Horizon™ fenestrated screws have the same or similar indications, intended use, same or similar overall design, packaging, sterilization and materials as the following FDA primary predicate cleared in K171938 (S.E. 10/23/2017) and K170679 (S.E. 05/11/2017). The predicate and subject new fenestrated screws have the identical function and scientific fundamental technology.

There are no technology changes to the existing CD Horizon™ Fenestrated Screw Set devices or the associated existing bone cements. However, the CD Horizon™ Fenestrated Screw Set system, Medtronic HV-R™ Fenestrated Screw Cement and Kyphon™ Xpede™ Bone Cement labeling has been updated to reflect the same indications for use as the predicates Kyphon™ Xpede™ Bone Cement (K163032, S.E. 02/27/2017), Kyphon™ HV-R™ Bone Cement (K180700, S.E. 05/18/2018), Medtronic HV-R™ Bone Cement (K152604, S.E. 01/06/2016), CD Horizon™ Fenestrated Screw Set (K171938, S.E. 10/23/2017) and CD Horizon™ Fenestrated Screw Set (K170347, S.E. 04/04/2017).

VI. Performance Data:

In accordance with the 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. Medtronic believes that testing is not warranted for the subject devices as they do not present a new worst case when compared to the predicate devices. All existing predicate data previously provided in the predicate 510(k)s are still applicable.

VII. Conclusions

The subject CD Horizon™ Fenestrated Screw Set devices, Kyphon™ Xpede™ Bone Cement and Medtronic HV-R™ Fenestrated Screw Cement have shown through supporting information provided in this premarket notification to be substantially equivalent to the identified predicate devices.