January 10, 2020

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

Re: K193011
Trade/Device Name: CD Horizon™ Fenestrated Screw Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: October 28, 2019
Received: October 29, 2019

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. 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)*
K193011

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 (e.g. fracture or dislocation), spinal stenosis, curvatures (e.g. scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion. Additionally, CD Horizon™ Fenestrated Screws may be used for immobilization and stabilization when used for trauma (e.g., fracture or dislocation) with the usage of bone graft material left to the surgeon's discretion.

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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510(k) Summary
K193011
January 3, 2020

I. Company: Medtronic Sofamor Danek USA, Inc.
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Proprietary Trade Name:	CD Horizon™ Fenestrated Screw Set
Common Name:	Bone Screw, Pedicle Screw
Classification Name/	Thoracolumbosacral pedicle screw system
Regulation Numbers/	21 CFR 888.3070
Classification/	Class II
Classification Product Code	NKB

II. Predicate Devices:

Primary Predicate:
CD Horizon™ Fenestrated Screw Set (K170347, S.E. 04/04/2017)
Additional Predicate:
CD Horizon™ Spinal System (K182119, S.E. 08/29/2018)
Additional Predicate:
CD Horizon™ Fenestrated Screw Set (K152604, S.E. 01/06/2016 and K191148, S.E. 09/12/2019)
The 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. Please see Section IV for the complete Indications for Use.

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.

IV. Indications for Use:

CD Horizon™ Fenestrated Screw Set

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 (e.g., fracture or dislocation), spinal stenosis, curvatures (e.g., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or

failed previous fusion. Additionally, CD Horizon™ Fenestrated Screws may be used for immobilization and stabilization when used for trauma (e.g., fracture or dislocation) with the usage of bone graft material left to the surgeon's discretion.

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.

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

CD Horizon™ Fenestrated Screw Set devices have the same fundamental scientific technology; indications for use, intended use, design, material, levels of attachment as the predicate device. The CD Horizon™ Fenestrated Screw Set devices are intended to help provide immobilization and stabilization of spinal segments of the thoracic, and lumbar, or sacral spine for the indications stated above. The purpose of this submission is to expand the CD Horizon™ Fenestrated Screw Set current indications for use to include treatment of trauma (e.g., fracture or dislocation), with the usage of bone graft material left to the surgeon's discretion.

VI. Performance Data:

Published performance outcomes were provided in support of this application. This clinical data supports the use of CD Horizon™ Fenestrated Screw Set for treatment of trauma patients (e.g., fracture or dislocation), with the usage of bone graft material left to the surgeon's discretion. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

VII. Conclusion

Based upon the supporting documentation provided in the pre-market notification for the CD Horizon™ Fenestrated Screw Set, the modification to the trauma indication with usage of graft material left to the surgeon's discretion, has been demonstrated to be substantially equivalent to the cited predicate.