January 11, 2019

Medtronic Sofamor Danek USA, Inc.
Mr. Raphael McInnis
Senior Regulatory Affairs Manager
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K182928
Trade/Device Name: CD Horizon™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NQP, NKB, KWP, KWQ
Dated: October 19, 2018
Received: October 22, 2018

Dear Mr. McInnis:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182928

Device Name
CD Horizon™ Spinal System

Indications for Use *(Describe)*
The CD Horizon™ Spinal System with or without SEXTANT™ instrumentation is 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, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion. With the exception of DDD, the CD Horizon™ LEGACY™ 3.5mm rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK Rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD Horizon™ Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. Refer to the VERTEX™ Reconstruction System Package Insert for a list of the VERTEX™ indications of use.

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

December 19, 2018

I. Submitter:

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II. Device:

Name of Device: CD Horizon™ Spinal System

Classification Names:

- Thoracolumbosacral pedical screw system (21 CFR 888.3070);
- Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060); and,
- Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)

Classification: Class II

Product Codes: NQP, NKB, KWQ, KWP

III. Predicates:

Primary Predicate:

- CD Horizon™ Spinal System (4.5mm titanium rods, bone screws, set screws; K020709, SE 5/9/2002)

Additional Predicates:

- CD Horizon™ Spinal System (5.5mm titanium rods, bone screws, set screws; K042790, SE 11/4/2004)
- CD Horizon™ Spinal System (PEEK rods; K052609, SE 10/21/2005)
- CD Horizon™ Spinal System (Bone screws for PEEK rods, K050809, SE 06/14/2005)
- CD Horizon™ Spinal System (Set screws for PEEK rods; K061915, SE 07/25/2006)
- CD Horizon™ Spinal System (K182119, SE 08/29/2018)

These predicates have not been subject to a design-related recall. No reference devices were used in this submission.

IV. Product Description:

The subject CD Horizon™ Spinal System is a multiple component device to allow the surgeon to build an implant system to fit the patients' anatomical and physiological requirements. The subject CD Horizon PEEK Rods consist of polyetheretherketone (PEEK) rods, multi-axial bone screws (MAS) and set screws to create a variety of semi-rigid configurations. The purpose of this traditional 510(k) is to modify the indications for the CD Horizon™ Spinal System.

V. Indications for Use:

The CD Horizon™ Spinal System with or without SEXTANT™ instrumentation is 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, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.

With the exception of DDD, the CD Horizon™ LEGACY™ 3.5mm rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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The CD Horizon™ SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD Horizon™ Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. Refer to the VERTEX™ Reconstruction System Package Insert for a list of the VERTEX™ indications of use.

VI. Comparison of Technological Characteristics:

The subject CD Horizon PEEK Rods and associated pedicle screws consist of multiple components which allows the surgeon to build an implant construct to fit the individual patient's anatomical and physiological requirements. The spinal implant assembly consists of a combination of bone screws, set screws, and continuous, uniform polyetheretherketone (PEEK Optima LT1) Rods.

The subject CD Horizon ™ Spinal System has similar technological features as compared to the predicate devices.

- The subject devices employ the same fundamental technology and design as the predicate rods and screws.
- The subject devices are manufactured from the same material (titanium alloy, tantalum, and polyetheretherketone) as that of predicate devices
- The subject devices' sterilization methods are same as that of the predicate devices

This submission seeks to modify to the indications for use for the subject PEEK Rods to limit their use to supplemental fixation in interbody fusion procedures.

VII. Performance Data:

Non-Clinical Testing:

In order to demonstrate substantial equivalence to the predicate devices, mechanical testing was performed on the subject and predicate devices in accordance with ASTM F1717, Standard test Methods for Spinal Implant Constructs in a Vertebrectomy Model and ASTM F1798, Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Sub-assemblies Used in Spinal Arthrodesis Implants.

Mechanical testing included static and dynamic compression bending, and static torsion testing per ASTM F1717, and static axial grip, static torsional grip, and static and dynamic flexion/extension testing per ASTM F1798. Biomechanical cadaver testing was also performed.

Clinical Performance:

A retrospective study was conducted and demonstrated that CD Horizon™ Spinal System PEEK Rod constructs are substantially equivalent when used to provide supplemental fixation in interbody fusion procedures for the treatment of DDD.

Clinical literature was also provided to support the use of the CD Horizon™ PEEK Rod constructs as supplemental fixation for interbody cages for the treatment of DDD.

VIII. Conclusion:

Based on the mechanical test results, clinical literature, clinical data and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.