



Food and Drug Administration
10903 New Hampshire Avenue
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October 21, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Lila Joe
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K141604
Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: September 26, 2014
Received: September 29, 2014

Dear Ms. Joe:

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 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141604

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 (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 and/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 may also be used for the same indications as an adjunct to fusion. With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK 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 implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CDHORIZON® 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: degenerative disc disease (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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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CD HORIZON[®] Spinal System
510(k) Summary
September 26, 2014

- I. **Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
- Contact:** Lila Joe
Principal Regulatory Affairs Specialist
- II. **Proprietary Trade Name:** CD HORIZON[®] Spinal System
- III. **Classification Name:** Pedicle Screw Spinal System, Spinal Intervertebral Body Fixation Orthosis, and Spinal Interlaminar Fixation Orthosis (21 CFR 888.3070, 888.3060 and 888.3050)
- IV. **Classification:** Class III
- V. **Product Codes:** NKB, OSH, MNH, MNI, KWQ, KWP

VI. **Product Description**

The CD HORIZON[®] Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK[®] Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The CD HORIZON[®] Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt chromium molybdenum alloy, or medical grade PEEK OPTIMA-LTI. Certain CD HORIZON[®] Spinal System components may be coated with hydroxyapatite.

The purpose of this 510(k) is to add additional non-sterile rods to the CD HORIZON[®] Spinal System. The type of rods includes a series of tapered and straight rods. The subject rods are manufactured out of medical grade cobalt-chromium-molybdenum alloy.

The subject rods along with other components such as metal screws, hooks and other connecting components are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of thoracic, lumbar, and/or sacral spine.

VII. **Indications**

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 (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 and/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 may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK 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 implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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: degenerative disc disease (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.

VIII. **Summary of the Technological Characteristics**

The subject CD HORIZON® Spinal System rods have identical indications, intended use, fundamental scientific technology, materials, and similar design features as the CD HORIZON® Spinal System predicates previously cleared by FDA in K043488 (S.E. 03/21/2005), K113174 (S.E. 11/21/2011), K121680 (S.E. 07/05/2012), and primary predicate K132111 (S.E. 08/06/2013). Like the predicate CD HORIZON® Spinal System rods, the subject rods have diameters ranging from 4.75mm to 6.30mm and lengths of 500mm and 600mm.

IX. **Identification of Legally Marketed Devices**

The subject CD HORIZON® Spinal System indications, intended use, fundamental scientific technology, design features, sterilization, and materials are similar to Medtronic's CD HORIZON® Spinal System. These predicates include CD HORIZON® Spinal System K042025 (S.E. 08/25/2004), K043488 (S.E. 03/21/2005), K091974 (S.E. 09/02/2009), K113174 (S.E. 11/21/2011), K121680 (S.E. 07/05/2012), and K132111 (primary predicate, S.E. 08/06/2013)

X. **Discussion of the Non-Clinical Testing**

Mechanical Testing

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.

Design verification testing was completed in accordance with *ASTM F1798 – “Standard Guide to Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*. The tests completed were:

- Axial Grip Testing
- Axial Torsion Testing
- Flexion Extension Static Testing
- Flexion Extension Fatigue Testing

Construct compression bending fatigue testing was also completed in accordance with *ASTM F1717 – Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*.

The subject devices met the pre-determined acceptance criteria for all tests.

XI. **Conclusions Drawn from the Non-Clinical Tests**

No new risks have been introduced to the CD HORIZON® Spinal System by the addition of the subject rods, and the subject rods do not create a new worst case for the overall CD HORIZON® Spinal System. Therefore, Medtronic believes the subject CD HORIZON® Spinal System, including the subject rods, to be substantially equivalent to legally marketed predicate devices, including the predicate CD HORIZON® Spinal System.
