



Food and Drug Administration  
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August 6, 2014

Medtronic Sofamor Danek USA, Incorporated  
Mr. Tejas Patel  
Regulatory Affairs Specialist  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: K141494

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: July 10, 2014  
Received: July 11, 2014

Dear Mr. Patel:

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)  
K141494

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, 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 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® 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)

**Ronald P. Jean -S**

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**CD HORIZON® Spinal System**  
**510(k) Summary**  
**July, 2014**

**I. COMPANY:** Medtronic Sofamor Danek USA, Inc  
1800 Pyramid Place  
Memphis, Tennessee 38132

**II. CONTACT:** Tejas Patel  
Regulatory Affairs Specialist  
Telephone: (901) 344-1443  
Fax: (901) 346-9738

**III. PROPRIETARY  
TRADE NAME:** CD HORIZON® Spinal System

**IV. CLASSIFICATION NAMES:** Spinal Interlaminar Fixation Orthosis  
(21 CFR 888.3050)  
Spinal Intervertebral Body Fixation Orthosis  
(21 CFR 888.3060)  
Spondylolisthesis Spinal Fixation Orthosis  
(21 CFR 888.3070)  
Spinal Pedicle Fixation Orthosis  
(21 CFR 888.3070)  
Spinal Pedicle Fixation, For Degenerative  
Disc Disease Orthosis (21 CFR 888.3070)  
Adolescent Idiopathic Scoliosis Pedicle  
Screw Spinal System, (21 CFR 888.3070)

**COMMON NAME:** Spinal Fixation Appliance, Spinal Fixation  
Orthosis

**CLASS:** III (Pre-Amendment)

**PRODUCT CODE:** KWP, KWQ, MNH, MNI, NKB, & OSH

## **V. 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.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, CROSSLINK® Plates and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The purpose of this submission is to modify Medtronic's CD HORIZON Spinal System to add additional components to the system, specifically, modified multi-axial screws.

## **VI. 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 (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.

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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 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® 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.

#### **VII. Summary of the Technological Characteristics:**

The subject CD HORIZON® Spinal System has identical indications, intended use, fundamental scientific technology, materials and similar design features to the previously FDA cleared predicate, CD HORIZON® Spinal System K091974 (S.E. 09/02/2009). Like the predicate CD HORIZON® Spinal System multi-axial screws, the subject screws will be manufactured from medical grade titanium, titanium alloy, and cobalt chrome. Both the predicate and subject devices attach to a 4.75mm diameter rod. The screw diameters of the subject device fall within the range of previously cleared diameters of the predicate device

#### **VIII. 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 other legally marketed devices, specifically Medtronic's CD HORIZON® Spinal System K091974 (S.E. 09/02/2009). The indications for use are identical to those cleared most recently in K140276 (S.E. 03/13/2014).

**IX. Discussion of Non-Clinical Testing:**

A risk analysis of the device modifications was completed in accordance with Medtronic design control procedures. The risk analysis, which included an engineering rationale, demonstrated that the subject CD HORIZON® Spinal System does not introduce new issues of safety or effectiveness. No additional non-clinical testing was performed.

**X. Discussion of Clinical Testing:**

No clinical testing was performed.

**XI. Conclusion:**

A risk analysis was completed for the modifications to the subject devices. Based on the results and additional supporting documentation provided in this submission, the subject devices demonstrated substantial equivalence to the previously listed predicate devices.