DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 11, 2015

Medtronic Sofamor Danek USA, Incorporated
Mr. Michael A. Scott
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K150178
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, MNI, MNH, KWP, KWQ
Dated: January 23, 2015
Received: January 26, 2015

Dear Mr. Scott:

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,

Mark N. Melkerson -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K150178

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)*

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

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CD HORIZON® Spinal System
510(k) Summary
January 2015

I.	**Submitter:**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
	Contact:	Michael A. Scott Senior Regulatory Affairs Specialist
	Date Prepared:	January 23, 2015
II.	**Device**	
	Name of Device:	CD HORIZON® Spinal System
	Common Name:	Spinal Fixation System
	Regulatory Classification:	Class III (Pre-amendment)
	Regulation Number, Classification Name, Product Codes:	21 CFR 888.3070 Pedicle Screw Spinal System, NKB, OSH, MNI, MNH 21 CFR 888.3060 Spinal Intervertebral Body Fixation Orthosis, KWQ 21 CFR 888.3050 Spinal Interlaminal Fixation Orthosis, KWP
III.	**Predicate Device**	K142591 (S.E. 12/01/2014) CD HORIZON® Spinal System – Primary Predicate K132471 (S.E. 10/08/2013) CD HORIZON® Spinal System – Predicate 2, Additional Predicate K132328 (S.E. 12/06/2013) CD HORIZON® Spinal System – Predicate 3, Additional Predicate *The predicate devices have not been subject to a design related recall.*

IV. Device 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 510(k) submission is to add additional transverse hooks to the CD HORIZON® Spinal System. These additional transverse hooks contain two changes from the predicate 2, CD HORIZON Spinal System, 1) a modified hook blade angle, and 2) packaged sterile via gamma irradiation. The subject sterile transverse hooks along with other components such as metal rods, screws, 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. The subject transverse hooks are manufactured out of medical grade titanium alloy per ASTM F136.

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 (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.

VI. Comparison of Technological Characteristics with Predicate Device

The subject CD HORIZON® Spinal System transverse hooks have identical indications for use and intended use as the CD HORIZON® Spinal System primary predicate most recently cleared by the FDA in K142591 (S.E. 12/01/2014). Like the CD HORIZON Spinal System hooks found in the predicate 2 submission (K132471 {S.E. 10/08/2013}), the subject transverse hooks can accept both 5.5mm and 6.0mm diameter rods, have an anatomic design that mimics the posterior spinal elements and are used with other connecting components to help provide immobilization and stabilization of spinal segments as an adjunct to fusion. Additionally, the new transverse hooks are provided sterile identical to that of the predicate 3 devices found in K132328 (S.E. 12/06/2013). Therefore, the technological characteristics of the subject device are the same as the technological characteristics of the predicate devices.

VII. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the CD HORIZON® Spinal System devices was conducted in accordance with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" issued April, 23, 2013.

The subject CD HORIZON® Spinal System transverse hooks are permanent implants and will be classified as permanent, >30 day body contact according to with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The subject transverse hooks are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standard:

ASTM F136 – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.

The titanium alloy material used for the subject CD HORIZON® Spinal System Transverse Hooks has a long clinical history of use in similar medical devices. Therefore, no additional biocompatibility testing is required.

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. It was determined that subject devices do not represent a new worst case. An engineering rationale was used to demonstrate substantial equivalence. As a new worst case has not been indicated and an engineering rationale was deemed adequate to prove equivalence to the predicate device, no additional mechanical testing is required.

VIII. Conclusion

Based on a risk analysis, engineering rationale, and additional supporting documentation provided in the pre-market notification, the subject CD HORIZON® Spinal System are substantially equivalent to the following predicates: K142591 (S.E. 12/01/2014) – Primary Predicate, and additional predicates K132471 (S.E. 10/08/2013) - Predicate 2, and K132328 (S.E. 12/06/2013) – Predicate 3.