Dear Ms. Ronner:

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,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

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)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.
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CD HORIZON® Spinal System
510(k) SUMMARY
August 2016

I. Submitter
Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901)396-3133

Contact
Becky Ronner
Sr. Regulatory Affairs Specialist
Direct Telephone: (901) 399-2757

Date Prepared
August 22, 2016

II. Device

Name of Device
CD HORIZON® Spinal System

Common Name
Bone Screws, Pedicle Screws

Classification Name
Pedicle Screw Spinal System (21 CFR 888.3070)
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050)
Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

Classification
Class III Pre-Amendment

Product Codes
NKB, MNH, MNI, KWQ, KWP, OSH

Predicates
There are four (4) Predicates.

CDHORIZON®SpinalSystem
K113174, S.E. 11/21/2011 (Primary Predicate)
K031833, S.E. 09/03/2003 (Additional)
K102555, S.E. 11/17/2010 (Additional)
K152457, S.E. 10/27/2015 (Additional)

The predicates have not been subject to a design related recall.

III. Product Description

CDHORIZON®SpinalSystem
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 subject CD HORIZON® Solera™ Spinal System offers dual rod multi-axial screws (DRMAS) that have an opened head. The subject screws offer the ability to place two rods in parallel. The subject DRMAS are provided sterile.

IV. Indications for Use:

CD HORIZON® Spinal System

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
conneector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the
VERTEX® indications of use.

V. Comparison of Technological Characteristics
The primary predicate for the CD HORIZON® Solera™ Spinal System is the predicate
CD HORIZON® Spinal System (K113174, S.E. 11/21/2011).

The subject CD HORIZON® Solera™ Spinal System screws have the same indications,
similar intended use, and similar materials as the following FDA cleared predicates
K113174 (S.E. 11/21/2011) and similar K102555 (S.E. 11/17/2010). The predicate and
subject screws have the same function. The predicate CD HORIZON® bone screws are
similar to the subject CD HORIZON® Solera™ bone screws in materials, fundamental
scientific technology, and fundamental surgical technique. The main difference in the
design of the primary predicate and subject screws is in the number of rod slots in the
head of the primary predicate and subject bone screws.

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

Biocompatibility
The biocompatibility evaluation for the subject CD HORIZON® Solera™ Spinal System
bone screws was conducted in accordance with the FDA's Draft Guidance for Industry
and FDA Staff, Use of International Standard ISO-10993, Biological Evaluation Method

The subject screws are manufactured from:
The subject screws are permanent implants and will be classified as "Implant Devices - Tissue/bone - C Permanent (>30 days)" according to FDA's Draft Guidance for Industry and FDA Staff, Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing, issued April 23, 2013.

Cobalt chrome, titanium alloy, and commercially pure titanium have a long history of safe and effective use in the predicate spinal implants and/or other legally marketed spinal devices. Therefore, no new biocompatibility testing is required.

**Mechanical Testing**

In accordance with the Guidance for Industry and FDA Staff - Spinal System 510(k)'s, Medtronic has evaluated the subject screws to demonstrate substantial equivalence to the predicate devices.

Design verification testing for the subject bone screws was completed in accordance with

- ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model,

The tests completed were:

- Construct Static Compression (ASTM F1717)
- Construct Static Torsion (ASTM F1717)
- Construct Compression Fatigue (ASTM F1717)
- Axial Grip (ASTM F1798)
- Axial Torsional Grip (ASTM F1798)
- Flexion Extension Fatigue (ASTM F1798)
The subject screws met the pre-determined acceptance criteria for all tests. Therefore, Medtronic believes design verification testing demonstrated that the subject screws are substantially equivalent to the predicate Medtronic screws.

Design validation testing was performed and demonstrated that the subject devices performed as intended.

**VII. Conclusions**

Based on the test results and additional supporting information provided in this pre-market notification, Medtronic believes the subject devices demonstrated substantial equivalence to the legally marketed predicate devices.