DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Mr. Gregory K. Maschek
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

February 12, 2015

Re: K143569
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: December 15, 2014
Received: December 16, 2014

Dear Mr. Maschek:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143569

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

MEDTRONIC Sofamor Danek

CD HORIZON® Spinal System

December 2014

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901)396-3133
Fax: (901) 346-9738

Contact: Gregory Maschek
Regulatory Affairs Specialist
Direct Telephone: (901)344-1273

Date Prepared: December 15, 2014

II. Device

Name of Device:	CD HORIZON® Spinal System
Common Name:	Pedicle Screw System
Classification Names:	Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixtion Orthosis, Spinal Pedical Fixation, For Degenerative Disc Disease Orthosis, and Adolescent Idiopathic Scoliosis Pedicle Screw Spinal System. (21 CFR 888.3070, 888.3060, and 888.3050)
Class:	Class III (Pre-Amendment)
Product Code:	NKB, OSH, MNH, MNI, KWP, and KWQ

III. Predicate Devices:

CD HORIZON® Spinal System

Primary Predicate:

K143141 (S.E. 12/01/2014)

Additional Predicates:

K132328 (S.E. 12/06/2013)

K091974 (S.E. 09/02/2009)

K113174 (S.E. 11/21/2011)

K042025 (S.E. 08/25/2004)

K961633 (S.E. 12/05/1996)

K132639 (S.E. 11/25/2013)

K141494 (S.E. 08/06/2014)

K050439 (S.E. 03/24/2005)

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

IV. 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 Traditional 510(k) is to modify Medtronic's CD HORIZON® Spinal System to add additional components to the system, specifically, Top-Loading SOLERA® lateral connectors. The subject lateral connectors are a titanium implant that consists of a post and a top loading head interconnection feature for lateral connection to 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 (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 the Predicate Devices:

The subject CD HORIZON® Spinal System has the same indications, intended use, fundamental scientific technology, materials, and sterilization method as the previously FDA cleared predicates. The indications are identical to the recently FDA cleared CD HORIZON® Spinal System, 510(k) K143141 (S.E. 12/01/2014, primary predicate). Similar CD HORIZON® Spinal System devices were cleared in the following predicates:

- CD HORIZON® Spinal System (SOLERA® Side-loading and Closed Lateral Connectors), K132328 (S.E. 12/06/2013).
- CD HORIZON® Spinal System (Fixed Angle Screws (FAS) for use with 4.75mm rods) K091974 (S.E. 09/02/2009).

- CD HORIZON® Spinal System (Fixed Angle Screws (FAS) for use with 5.5/6.0mm rods) K113174 (S.E. 11/21/2011).
- CD HORIZON® Spinal System (Multi Axial Screws (MAS) for use with 6.35mm rods and 4.5mm rods) K042025 (S.E. 08/25/2004).
- CD HORIZON® Spinal System (to show top loading connectors are existing within the CD HORIZON® Spinal System) K961633 (S.E. 12/05/1996).
- CD HORIZON® Spinal System (for labeling reference to the existing Medtronic Reusable Instrument Instructions for Use (IFU)) K132639 (S.E. 11/25/2013).
- CD HORIZON® Spinal System (for labeling reference to the previously cleared SOLERA® Surgical Technique) K141494 (S.E. 08/06/2014).
- CD HORIZON® Spinal System (for labeling reference to the previously cleared Iliac Surgical Technique) K050439 (S.E. 03/24/2005).

VII. Performance Data:

The following information is provided in support of substantial equivalence.

Biocompatibility

The subject CD HORIZON® Spinal System implants are permanent implants and will be classified as permanent , >30 day body contact according to 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 implants are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standard:

- ASTM F136: Standard Specification for Wrought Ti-6Al-4V ELI Alloy for Surgical Implant

The titanium alloy has a long history of safe and effective use in predicate spinal implants and biocompatibility testing is not required.

Mechanical Testing

Non-clinical mechanical testing was performed in accordance with ASTM F1798 including Axial Grip, Axial Torsion and Flexion Extension Fatigue Testing. The subject devices met the pre-determined acceptance criteria.

VIII. Conclusion:

A risk analysis was completed and non-clinical mechanical testing was performed in accordance with ASTM F1798. Based on the test results and additional supporting information provided in this pre-market notification, the CD Horizon Spinal System is substantially equivalent to the following predicates:

- CD HORIZON® Spinal System

  Primary Predicate:

  - K143141 (S.E. 12/01/2014)

  Additional Predicates:

  - K132328 (S.E. 12/06/2013)
  - K091974 (S.E. 09/02/2009)
  - K113174 (S.E. 11/21/2011)
  - K042025 (S.E. 08/25/2004)
  - K961633 (S.E. 12/05/1996)
  - K132639 (S.E. 11/25/2013)
  - K141494 (S.E. 08/06/2014)
  - K050439 (S.E. 03/24/2005)