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Medtronic Sofamor Danek USA, Incorporated  
Ms. Becky Ronner  
Senior Regulatory Affairs Specialist  
1800 Pyramid Place  
Memphis, Tennessee 38132

November 5, 2015

Re: K152248  
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: August 7, 2015  
Received: August 10, 2015

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 Parts 801 and 809); 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

## Indications for Use

510(k) Number (if known)

K152248

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****August 2015**

Submitter:	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Becky Ronner Senior Regulatory Affairs Specialist Direct Telephone: (901)399-2757
Date Prepared	August 7, 2015
Name of Device	CD HORIZON® Spinal System
Common Name	Rods, Extenders, Reducers and Inserters
Trade Name	CD HORIZON® Spinal System
Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	<ul style="list-style-type: none"> <li>• Class III</li> <li>• 21 CFR 888.3050 Spinal Interlaminar Fixation Orthosis; KWP</li> <li>• 21 CFR 888. 3060 Spinal Intervertebral Body Fixation Orthosis; KWQ</li> <li>• 21 CFR 888.3070 Pedicle Screw System; MNH, MNI, NKB, OSH</li> </ul>
Predicate Devices	<p>K143375 CD HORIZON® Spinal System (S.E 2/13/2015) – Primary Predicate</p> <p>Additional Predicates:</p> <p>K113174 CD HORIZON® Spinal System (S.E 11/21/2011)  K122862 CD HORIZON® Spinal System (S.E 10/03/2012)  K132639 CD HORIZON® Spinal System (S.E 11/25/2013)  K102807 CD HORIZON® Spinal System (S.E 11/17/2010)</p> <p><i>The predicates have not been subject to a design related recall.</i></p>
Description of Devices	<p>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 devices include:</p>

	<ul style="list-style-type: none"> <li>• Rods</li> <li>• Extenders</li> <li>• Sequential Reducer</li> <li>• Inserters</li> <li>• Modified Labeling (surgical techniques and disassembly/assembly instructions)</li> <li>• Accessories, cases, caddies, trays, and lids which may be used to transport and sterilize the subject implants and instruments.</li> </ul> <p>The subject CD HORIZON® Spinal System devices will be available in similar sizes as the predicate systems.</p>
<p>Indications for Use</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>

	<p>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.</p> <p>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.</p> <p>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.</p>
<p>Comparison of Technological Characteristics with the Predicate Devices:</p>	<p>The CD HORIZON® Spinal System has the same fundamental technology and the same cobalt chrome, titanium and stainless steel materials as the predicate devices. Additionally, acetal is commonly used for handles of instruments used in spinal surgery. The predicate and subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic lumbar and/or sacral spine.</p> <ul style="list-style-type: none"> <li>• K143375 CD HORIZON® Spinal System (S.E 2/13/2015) – Primary Predicate</li> <li>• K113174 CD HORIZON® Spinal System (S.E 11/21/2011)</li> <li>• K122862 CD HORIZON® Spinal System (S.E 10/03/2012)</li> <li>• K132639 CD HORIZON® Spinal System (S.E 11/25/2013)</li> <li>• K102807 CD HORIZON® Spinal System (S.E 11/17/2010)</li> </ul>
<p>Performance Data:</p>	<p>The following performance data were provided in support of substantial equivalence.</p> <p><b>Biocompatibility</b></p> <p>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.</p>

The subject CD HORIZON® Spinal System rods are permanent implants and are 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 rods are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards:

- **ASTM F1537** – Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants
- **ASTM F136** – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

The CD HORIZON® Spinal System extender, sequential reducer, and inserters are external communicating devices and are classified as limited, up to 24 hours of 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". These instruments are manufactured from the same medical grade stainless steel as the predicate devices in accordance with the following ASTM standards:

- **ASTM F899** – Standard Specification for Wrought Stainless Steel for Surgical Instruments
- **ASTM A564** – Standard Specification for Hot-Rolled and Cold Finished Age-Hardening Stainless Steel Bars and Shapes
- **ASTM A693** – Standard Specification for Precipitation-Hardening Stainless and Heat-Resisting Steel Plate, Sheet and Stripe
- **ASTM A276** – Standard Specification for Stainless Bars and Shapes

Additionally, the handle of subject inserter which has indirect patient contact is manufactured from acetal in accordance with ASTM F1855 – "Standard Specification for Polyoxymethylene

	<p>(Acetal) for Medical Applications” with Celcon M25 Dark Blue colorant. This material is surface material and is classified as limited, up to 24 hours of body contact according to the 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.</p> <p>Cobalt Chrome, Commercially Pure Titanium, Titanium Alloy, medical grade stainless steel and acetal have a long history of safe and effective use in spinal surgery, and biocompatibility testing is not required and no testing was conducted.</p> <p><b>Mechanical Testing</b></p> <p>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. A combination of engineering rationales and testing were used to establish substantial equivalence. The following bench testing was completed and the tests met the predetermined acceptance criteria:</p> <ul style="list-style-type: none"> <li>• Static Reduction Testing <ul style="list-style-type: none"> <li>○ Sample size was determined based on ASTM F1717</li> </ul> </li> <li>• Cantilever Load testing</li> <li>• Torsional Load Testing</li> </ul>
Conclusion:	<p>Based on the risk analysis, test results, and additional supporting documentation provided in the pre-market notification, the subject CD HORIZON® Spinal System are as safe and effective as the following predicates:</p> <ul style="list-style-type: none"> <li>• K143375 CD HORIZON® Spinal System (S.E 2/13/2015) - (Primary Predicate)</li> <li>• K113174 CD HORIZON® Spinal System (S.E 11/21/2011)</li> <li>• K122862 CD HORIZON® Spinal System (S.E 10/03/2012)</li> <li>• K132639 CD HORIZON® Spinal System (S.E 11/25/2013)</li> <li>• K102807 CD HORIZON® Spinal System (S.E 11/17/2010)</li> </ul>