



Food and Drug Administration
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Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Inc.
Mr. Justin E. O'Connor
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

December 20, 2016

Re: K163301
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: November 21, 2016
Received: November 22, 2016

Dear Mr. O'Connor:

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

510(k) Number (if known)

K163301

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 November 2016

I. Submitter

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

Contact: Justin E. O'Connor
Regulatory Affairs Specialist

Date Prepared: November 21, 2016

II. Subject Device

Name of Device: CD HORIZON® Spinal System

Regulatory Number, Class, Codes: 21 CFR 888.3070 Pedicle Screw Spinal System,
NKB, MNH, MNI, OSH
21 CFR 888.3050 Spinal Interlaminar Fixation
Orthosis, KWP
21 CFR 888.3060 Spinal Intervertebral Body
Fixation Orthosis, KWQ

Common Name: Pedicle Screw Spinal System, Spinal Interlaminar
Fixation Orthosis,

Class: Class III (Pre-Amendment)

III. Predicate Devices:

K132471 (S.E. 10/08/2013) CD HORIZON®
Spinal System – Predicate 1, Primary Predicate
K150178 (S.E. 02/11/2015) CD HORIZON®
Spinal System – Predicate 2, Additional Predicate
K153589 (S.E. 02/10/2016) CD HORIZON®
Spinal System – Predicate 3, Additional Predicate

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 submission is to modify Medtronic's CD HORIZON® Spinal System to add additional components to the system, specifically non-sterile 30° and 45° Transverse Hooks. The subject transverse hooks have the same intended use, indications, material, sizes, levels of attachment, fundamental scientific technology, and sterilization method as the following FDA cleared CD HORIZON® Spinal System predicates: primary predicate 1 (K132471, S.E. 10/08/2013), predicate 2 (K150178, S.E. 02/11/2015), and predicate 3 (K153589, S.E. 02/10/2016).

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 have the same intended use, indications, fundamental scientific technology, material, and sterilization method as the previously FDA cleared predicates. Both the subject and predicate hooks are based on the same

technological characteristics of providing posterior, non-cervical fixation as an adjunct fusion for degenerative disc disease, spondylolisthesis, trauma, spinal stenosis, curvatures, tumor, pseudarthrosis, and/or failed previous fusion. Both the subject and predicate hooks connect to 5.5mm/6.0mm rods that have been placed in T1-S1 region of the spine and are secured to the rods using set screws, which complete the construct. The only difference in technological characteristics is that the subject hooks have a transition offset that falls outside of the cleared range of the predicates but does not raise any issues of safety and effectiveness. Therefore, the technological characteristics of the subject hooks are identical to the predicate hooks.

VII. Performance Data:

The following information is provided in support of substantial equivalence.

Biocompatibility

The subject transverse hooks are manufactured from same titanium alloy (Ti-6Al-4V ELI) material as the predicates. Titanium alloy has a long history of safe and effective use in similar spinal implants. Therefore, no additional biocompatibility testing is not required.

Mechanical Testing

In accordance with, “Guidance for Industry and FDA Staff – Spinal System 510(k)’s”, Medtronic has evaluated the subject transverse hooks to demonstrate substantial equivalence to the predicate devices. Medtronic completed both an engineering rationale and a risk analysis in accordance with Medtronic design control procedures. Both evaluations demonstrated that the subject hooks do not introduce a new worst case to the CD HORIZON® Spinal System. Therefore, no new mechanical testing was required for this submission.

VIII. Conclusion:

Based on the engineering rationale, risk analysis, and other supporting documentation provided in this pre-market notification, the subject 30° and 45° Transverse Hooks are proven to be substantially equivalent to the following predicates:

- K132471 (S.E. 10/08/2013) – Predicate 1 (Primary Predicate)
 - K150178 (S.E. 02/11/2015) – Predicate 2 (Additional Predicate)
 - K153589 (S.E. 02/10/2016) – Predicate 3 (Additional Predicate)
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