August 29, 2018

Medtronic Sofamor Danek USA, Inc.
Ankit K. Shah
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K182119
Trade/Device Name: CD HORIZON™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: August 3, 2018
Received: August 6, 2018

Dear Mr. Shah:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182119

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 (DDD - 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 DDD, 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, pseudarthosis, 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: DDD (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 2018

I. **Submitter**

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Memphis, Tennessee 38132
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Contact: Ankit K. Shah
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Phone: (901) 344-1272

Date Prepared: August 29, 2018

II. Device

Name of Device: CD HORIZON™ Spinal System

Classification Names: Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)

Class: Class II

Product Code: NKB, KWP, KWQ

III. **Predicate Devices:**

Primary Predicate:

- CD HORIZON Spinal System, K090390 (S.E. 05/15/2009)

Additional Predicates:

- CD HORIZON Spinal System, K113174 (S.E. 11/21/2011)
- CD HORIZON Spinal System, K132328 (S.E 12/06/2013)
- CD HORIZON Spinal System, K091974 (S.E. 09/02/2009)

Reference Predicate:

- Artic-L 3D Ti Spinal System with Tionic, K171689 (S.E. 10/05/2017)

Reference predicates have been mentioned in certain sections.

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 Special 510(k) is to add additional components to the Medtronic's CD HORIZON™ Spinal System. The devices being added are sterile domino connectors made using Titanium Alloy.

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 (DDD - 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 DDD, 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, pseudarthosis, 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: DDD (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 and the fundamental technology is identical to the FDA cleared CD HORIZON™ Spinal System, 510(k) K090390 (S.E. 05/15/2009). Other features and materials of the device within this subject CD HORIZON Spinal System submission are identical to the following predicates:

Predicate 2: CD HORIZON Spinal System, K113174 (S.E. 11/21/2011)
Predicate 3: CD HORIZON Spinal System, K132328 (S.E 12/06/2013)
Predicate 4: CD HORIZON Spinal System, K091974 (S.E. 09/02/2009)

Reference Predicate:
Predicate 5: Artic-L 3D Ti Spinal System with Tionic, K171689 (S.E. 10/05/2017)

VII. Performance Data:

The following information is provided in support of substantial equivalence.

Biocompatibility

The subject CD HORIZON™ Spinal System implants are permanent implants (> 30 days) and will be classified as body contacting devices 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 standards:

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

The mateials used for manufacturing the subject device have 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 not performed on the sterile implants. The subject implants are identical to the predicate devices in terms of material, rod compatibility sizes, rod interconnection features, intended use and indications for use. The predicate devices were tested in accordance to ASTM F1798 including Axial Grip, Axial Torsion and ASTM F1717 static compression, static torsion and compression fatigue. The subject devices do not introduce a new worst case, hence testing conducted on predicate devices is sufficient for subject rods and are substantially equivalent to the predicate device.

Non-Pyrogenicity Endotoxin Testing

The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case subject implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed, and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

VIII. Conclusion:

A risk analysis was completed, and the modified Domino Connectors do not introduce a new worst case. Based on the test results and additional supporting information provided in this pre-market notification, the subject CD Horizon™ Spinal System is substantially equivalent to the following predicates:

Primary Predicate

Predicate 1: CD HORIZON Spinal System, K090390 (S.E. 05/15/2009)

Additional Predicates:

Predicate 2: CD HORIZON Spinal System, K113174 (S.E. 11/21/2011)

Predicate 3: CD HORIZON Spinal System, K132328 (S.E 12/06/2013)

Predicate 4: CD HORIZON Spinal System, K091974 (S.E. 09/02/2009)

Reference Predicate:

Predicate 5: Artic-L 3D Ti Spinal System with Tionic, K171689 (S.E. 10/05/2017)