January 15, 2021

Medtronic Sofamor Danek USA, INC.
Madhuvanthi Soundirarajan
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K203678
Trade/Device Name: CD HORIZON™ Spinal System
Regulation Number: 21 CFR 8888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NQP, NKB, KWP, KWQ
Dated: December 17, 2020
Received: December 17, 2020

Dear Madhuvanthi Soundirarajan:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K203678

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™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

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.

510(k) Summary

MEDTRONIC
CD HORIZON™ Spinal System

November 2020

I. Submitter	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Madhuvanthi Soundirarajan Regulatory Affairs Specialist Email: madhuvanthi.soundirarajan@medtronic.com Telephone: (352)-433-9130
Date Prepared	December 2020
II. Name of Device	CD HORIZON™ Spinal System
Common Name	Thoracolumbosacral Pedicle Screw System, Spinal Fixation Orthosis, Spinal Fixation Appliance
Classification Name	Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070) Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050) Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Classification	Implants: Class II
Product Codes	NQP (888.3070); NKB (888.3070)
Subsequent Codes	KWP (888.3050), KWQ (888.3060)
III. Predicate Devices	**Predicate 1 (Primary Predicate)**- CD HORIZON™ Spinal System- K182928 (S.E. 01/11/2019) **Predicate 2**: CD HORIZON™ Spinal System – K182119 (S.E. 08/29/2018) **Predicate 3**: CD HORIZON™ Spinal System – K140449 (S.E. 03/25/2014)
IV. Description	The subject CD HORIZON™ Spinal System consists of non-sterile domino connectors, made of Titanium Alloy, that are used to provide the surgeon with an efficient construct extension as

	well as connection options for multi-rod spinal constructs. The subject CD HORIZON™ Spinal System includes 1. Non-sterile Domino connectors 2. Trays and lid
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 titanium, cobalt chrome, and stainless steel implants 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 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 titanium, cobalt chrome, and stainless steel 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™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have

	up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use. 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 and the primary predicate have identical intended use, indications, levels of attachment, and fundamental scientific technology. The subject devices have the same intended use, material, and fundamental technology as the predicate 2 domino connectors. The subject domino connectors and the predicate 2 domino connectors have identical rod compatibility, material, length, height, width, and thread form for set screw use. The only difference between the subject domino connectors and the predicate 2 is that the subject domino connectors will be provided non-sterile, which is identical to predicate 3 domino connectors. Like the predicate 3 domino connectors, the subject domino connectors will be provided non-sterile, intended to be steam sterilized by the end user. By providing the subject domino connectors non-sterile, the safety and effectiveness of the device is not affected since the predicate 3 CD Horizon™ Spinal System has similar domino connectors with identical sterilization method. Please see the **Substantial Equivalence** section of this submission for more detail.

VII. Performance Data	**Mechanical Testing** The purpose of this submission is to take the existing sterile domino connector designs, cleared in the predicate 2, and provide them non-sterile. The subject domino connectors are being created to provide additional rod connector options for surgeon convenience. No design changes have been made to the subject devices as a result of this submission. The subject devices remain identical to the designs cleared in the predicate 2 with the same intended use, materials, and fundamental technology. As a result, the subject CD HORIZON™ Spinal System does not represent a new worst case; therefore, no new bench performance testing is warranted. Please see the **Bench Performance Testing** section of this submission for more detail. **Biocompatibility** Identical to the predicate devices, the subject domino connectors are made of Titanium Alloy. This material is considered biocompatible due to its long history of clinical use in medical devices. Please see the **Biocompatibility** section of this submission for more detail.
VIII. Conclusion	Based on the supporting evidence provided, Medtronic believes the subject devices are substantially equivalent to the below predicates. • **Predicate 1 (Primary Predicate)**: CD HORIZON™ Spinal System – K182928 (S.E. 01/11/2019) • **Predicate 2**: CD HORIZON™ Spinal System – K182119 (S.E. 08/29/2018) • **Predicate 3**: CD HORIZON™ Spinal System – K140449 (S.E. 03/25/2014)