September 8, 2020

Medtronic Sofamor Danek USA, Inc.
Venkata Sandeep Manne
Associate Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K202328
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 10, 2020
Received: August 17, 2020

Dear Mr. Manne:

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, MBE
Assistant Director
DHT6B: Division of Spine 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)*
K202328

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 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.

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 USA, Inc.

CD HORIZON™ Spinal System

August 2020

I.	**Submitter**	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133
	Contact:	Venkata Sandeep Manne Associate Regulatory Affairs Specialist Email: venkatasandeep.manne@medtronic.com
	Date Prepared:	August 10, 2020
II.	**Subject Device**	
	Name of Device:	CD HORIZON™ Spinal System
	Product Codes:	NKB, KWP, KWQ
	Common name:	Spinal Fixation Appliance, Spinal Fixation Orthosis
	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	Class II
III.	**Predicate Devices:**	**Predicate 1 (Primary Predicate):** CD HORIZON™ Spinal System- K182928 (S.E. 01/11/2019) **Predicate 2 (Additional Predicate):** CD HORIZON™ Spinal System- K113174 (S.E. 11/21/2011) **Predicate 3 (Additional Predicate):** CD HORIZON™ Spinal System- K162379 (S.E.11/16/2016) *The predicate devices were not subjected to any 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. Similar 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.
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. When used with 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 have the same intended use, indications, fundamental scientific technology, material, and sterilization method as the previously FDA cleared CD HORIZON™ Spinal System predicates. The primary difference between predicate devices and subject devices is that the subject devices are provided Sterile. The materials, thread forms, and sizes of the subject devices fall within the cleared range of the CD HORIZON™ Spinal system predicate devices and does not raise any issues on safety and effectiveness. Both Subject and Predicate devices are based on the same technological characteristics of providing 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. The design features, materials and indications for use of the subject devices are substantially equivalent to the previously cleared predicates CD HORIZON™ Spinal System K182928(S.E. 01/11/2019), and CD HORIZON™ SOLERA™ Spinal System K113174 (S.E. 11/21/2011) Therefore, the technological characteristics of the subject devices are identical to the predicate devices. The subject devices are provided gamma sterilized similar to the predicate devices cleared in CD Horizon™ Spinal system K162379 (S.E.11/16/2016).
VII.	**Performance Data**	**Mechanical Testing:** 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. Medtronic completed both an engineering rationale and a risk analysis in accordance with Medtronic design control procedures. Both

		evaluations demonstrated that the subject devices do not introduce a new worst case to the CD HORIZON™ Spinal System. **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 Titanium – 6Aluminum – 4Vanadium ELI (Extra-Low-Interstitial) Alloy for Surgical Implants • ASTM F67 - Standard Specification for Unalloyed Titanium for Surgical Implant Applications • ASTM F1537 - Standard Specification for Wrought Cobalt – 28Chromium 6Molybdenum Alloys for Surgical Implants. The materials used for manufacturing the subject device have a long history of safe and effective use identical to predicate spinal implants. **Bacterial 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.	**<u>Conclusion:</u>**	Based on the supporting information provided in this pre-market notification, the subject CD Horizon™ Spinal System is substantially equivalent to the following predicates: • Predicate 1 (Primary Predicate) CD HORIZON™ Spinal System K182928 (S.E. 01/11/2019) • Predicate 2 (Additional Predicate) CD HORIZON™ Spinal System K113174 (S.E. 11/21/2011) • Predicate 3 (Additional Predicate) CD HORIZON™ Spinal System K162379 (S.E.11/16/2016)