Medtronic Sofamor Danek USA, Inc.
Kelly Mcdonnell
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

July 21, 2021

Re: K211958
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: June 23, 2021
Received: June 24, 2021

Dear Kelly Mcdonnell:

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 and Part 809); 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,

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211958

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, CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, 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. Devices are 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, spondylolisthesis, trauma, and/or tumor.

To achieve additional levels of fixation, 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 Vertex™ indications.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

MEDTRONIC Sofamor Danek USA, Inc.

CD Horizon™ Spinal System

July 20, 2021

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Contact: Kelly McDonnell
Sr. Regulatory Affairs Specialist
Email: kelly.m.mcdonnell@medtronic.com

Date Prepared: June 23, 2021

II. Subject Device

Name of Device:	CD Horizon™ Spinal System
Product Codes:	NKB, KWP, KWQ
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	Class II

III. Predicate Devices:

Primary Predicate: CD Horizon™ Spinal System K182119 (SE 08/29/2018)
Additional Predicate 1: CD Horizon™ Spinal System K042025 (SE 08/25/2004)
Additional Predicate 2: CD Horizon™ Spinal System K210637 (SE 04/30/2021)
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 3.5 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.

Certain components within the CD Horizon™ Spinal System are specifically excluded for use in pediatric patients. These include PEEK rods, Shape Memory Alloy Staples, Spire™ plates, and Dynalok™ bolts. Screws used in pediatric cases are only cleared for use via a posterior approach. Components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, and medical grade cobalt-chromium-molybdenum alloy.

Certain implant components from other Medtronic spinal systems can be used with the CD Horizon™ Spinal System in non- pediatric cases. These components include TSRH™ rods, hooks, screws, plates, Crosslink™ plates, connectors, staples and washers, GDLH™ rods, hooks, connectors and Crosslink™ bar and connectors; Liberty™ rods and screws; Dynalok™ Plus and Dynalok Classic™ bolts along with rod/bolt connectors; and Medtronic multi-axial rods and screws. Note: certain components are specifically designed to connect to specific rod diameters, while other components can connect to multiple rod

diameters. Care should be taken so the correct components are used in the spinal construct.

CD Horizon™ hooks are intended for posterior use only. CD Horizon™ staples and CD Horizon™ Eclipse™ rods and associated screws are intended for anterior use only. However, for patients of smaller stature and pediatric patients, CD Horizon™ 4.5mm rods and associated components may be used posteriorly.

CD Horizon™ Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK Optima-LT1. Certain CD Horizon™ Spinal System components may be coated with hydroxyapatite. No warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct. The CD Horizon™ Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory

Alloy is compatible with titanium, titanium alloy, and cobalt-chromium-molybdenum alloy. Do not use with stainless steel. These staples are not to be used in pediatric patients.

PEEK Optima-LT1 implants may be used with titanium or cobalt-chromium-molybdenum alloy implants. CD Horizon™ PEEK rods are not to be used in pediatric patients. PEEK rods are only to be used with the associated pedicle screws as well as interbody fusion devices in the anterior spinal column.

To achieve best results, do not use CD Horizon™ Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the CD Horizon™ Spinal System components should ever be reused under any circumstances.

The changes/ modifications to the CD Horizon™ Spinal System presented in this submission are:

- Introduction of Revision Connectors which have modifications to the primary predicate device geometry offering additional options for rod size and screw trajectory connections.
- Cross-compatibility is presented for use of the insertion devices presented in K210637 (S.E. 04/30/2021) for use with implants presented in K201407 (S.E. 09/10/2020).

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, CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, 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. Devices are intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

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intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD, spondylolisthesis, trauma, and/or tumor.

To achieve additional levels of fixation, 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 Vertex™ indications.

VI. **Comparison of Technological Characteristics with the Predicate Devices**

The subject CD Horizon™ Spinal System Revision Connector implants have the same indications, intended use, fundamental scientific technology, materials, sterilization method, and similar design as the previously FDA cleared predicates CD Horizon™ Spinal System K210637 (S.E. 04/30/2021). Please refer to the substantial equivalence section of this submission for more details.

The indications for use for the subject connector devices are identical to the previously cleared CD Horizon™Spinal System K210637 (S.E. 04/30/2021).

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 performed confirmatory mechanical testing per ASTM F1798 and ASTM F1717 and a risk analysis in comparison to predicate devices. Both evaluations demonstrated that the subject devices do not introduce a new worst case to the CD Horizon™ Spinal System product families.

Biocompatibility:

The subject CD Horizon™ Spinal System Revision Connector implants are permanent implants (> 30 days) and are 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

The materials used for manufacturing the subject device have a long history of safe and effective use identical to predicate devices and biocompatibility testing is not required.

VIII. **Conclusion:**

Based on the supporting information provided in this pre-market notification, the subject CD Horizon™ Spinal System Revision Connector implants are substantially equivalent to the following predicates:

- Primary Predicate: CD Horizon™ Spinal System K182119 (SE 08/29/2018)
- Additional Predicate 1: CD Horizon™ Spinal System K042025 (SE 08/25/2004)
- Additional Predicate 2: CD Horizon™ Spinal System K210637(SE 04/30/2021)