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

August 16, 2023

Re: K232141
Trade/Device Name: CD Horizon™ ModuLeX™ FNS Screw Set (Fenestrated Screw); CD Horizon™ ModuLeX™ Spinal System (Modular Extended Tab Head)
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: July 18, 2023
Received: July 18, 2023

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); 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,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2023.08.16 08:57:52 -04'00' 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.

Submission Number *(if known)*

K232141

Device Name

CD Horizon™ ModuLeX™ FNS Screw Set (Fenestrated Screw);
CD Horizon™ ModuLeX™ Spinal System (Modular Extended Tab Head)

Indications for Use *(Describe)*

CD Horizon Fenestrated Screw Set

When used without cement, CD Horizon™ Fenestrated Screws (with or without Sextant™ or Longitude™ instrumentation) are 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, tumor and/or trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.

Additionally, CD Horizon™ Fenestrated Screws may be used for immobilization and stabilization when used for trauma (e.g., fracture or dislocation) with the usage of bone graft material left to the surgeon's discretion.

When used in conjunction with Kyphon™ HV-R™ Bone Cement or Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic, lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD Horizon™ Fenestrated Screws augmented with Kyphon™ HV-R™ Bone Cement or Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

CD Horizon Spinal System

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.

510(k) Summary
MEDTRONIC Sofamor Danek USA, Inc.
August 15, 2023

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Contact: Kelly McDonnell
Principal Regulatory Affairs Specialist
Email: kelly.m.mcdonnell@medtronic.com
Tel : 901-396-3133
Date Prepared: July 18, 2023

II. Subject Device

Name of Device: CD Horizon™ ModuLeX™ FNS Screw Set (Fenestrated Screw); CD Horizon™ ModuLeX™ Spinal System (Modular Extended Tab Head)
Product Codes: NKB, KWP, KWQ
Common name: Thoracolumbosacral Pedicle Screw System, Spinal interlaminal fixation orthosis, Spinal intervertebral body 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:

Primary Predicate: CD Horizon™ Fenestrated Screw Set K201362 (SE 08/19/2020)
Additional Predicate: CD Horizon™ Spinal System K221244 (SE 05/25/2022)
The predicate devices were not subjected to any Recall.

IV. Description

CD Horizon™ Fenestrated Screw Set

The CD Horizon™ Fenestrated Screw Set consists of a variety of cannulated screws. These screws contain a series of fenestrations which allows polymethylmethacrylate (PMMA) bone cement (Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement) to be injected into the treated site. This cement is used to augment screw fixation into the pedicle in patients whose life expectancy is of insufficient duration to permit achievement of fusion.

These implants may also serve as traditional pedicle screws when used without bone cement in patients.

CD Horizon™ Fenestrated Screws are specifically designed to connect to appropriate rods and associated connecting components

contained within the CD Horizon™ Spinal System. Refer to the CD Horizon™ Spinal System package insert for information regarding those implants. Care should be taken so the correct components are used in the spinal construct.
CD Horizon™ Fenestrated Screw Set implant components are fabricated from medical grade titanium and/or medical grade titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy. Never use stainless steel and titanium implant components in the same construct.
Do not use CD Horizon™ Fenestrated Screw implants with components from any system other than the CD Horizon™ Spinal System.

CD Horizon™ Spinal System
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.
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.

V. Indications for use

CD Horizon™ Fenestrated Screw Set
When used without cement, CD Horizon™ Fenestrated Screws (with or without Sextant™ or Longitude™ instrumentation) are 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, tumor and/or trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.
Additionally, CD Horizon™ Fenestrated Screws may be used for immobilization and stabilization when used for trauma (e.g., fracture or dislocation) with the usage of bone graft material left to the surgeon's discretion. When used in conjunction with Kyphon™ HV-R™ Bone Cement or Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic, lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD Horizon™ Fenestrated Screws

augmented with Kyphon™ HV-R™ Bone Cement or Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

CD Horizon™ Spinal System

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.

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

The subject CD Horizon™ ModuLeX™ FNS Screw Set fenestrated screw shanks and CD Horizon™ ModuLeX™ Spinal System screw heads with extended tabs are spinal fixation implants that have the same indications, intended use, fundamental scientific technology, materials, sterilization method, and similar design as the previously FDA cleared predicates. The main technological difference between the subject screws and the primary predicate devices is the modularity feature, where heads may be assembled to the shank at the point of use.

VII. **Performance Data**

Mechanical/ Bench Testing:
In accordance with, "Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic evaluated the subject implants in comparison to the predicate devices tested per ASTM F1798 and ASTM F1717. It was determined that the subject devices have similar design features in comparison to the predicate devices and do not present a new worst-case. A risk analysis was performed comparing the subject implants to the primary predicate devices, which additionally identified that there is no increased risk as a result of providing the fenestrated shanks and extended tab heads for use in a modular workflow. The fenestration features of the subject screw shanks were determined to be substantially equivalent to the predicates and minor differences will not impact cement delivery. Therefore, mechanical stability of the subject devices has been deemed equivalent to the predicate devices.

VIII. **Conclusion:**

Based on the supporting information provided in this pre-market notification, the subject fenestrated screw implants are substantially equivalent to the following predicates:

- Primary Predicate: CD Horizon™ Fenestrated Screw Set K201362 (SE 08/19/2020)
- Additional Predicate: CD Horizon™ Spinal System K221244 (SE 05/25/2022)