



April 30, 2021

Medtronic
Shweta Sharma
Principal Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K210637

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, OLO, HBE
Dated: March 2, 2021
Received: March 3, 2021

Dear Shweta Sharma:

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

Indications for Use

510(k) Number (if known)

K210637

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

K210637

Device Name

Navigated CD Horizon™ Spinal System Instruments

Indications for Use (Describe)

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC™ Powerease™ System.

Do not implant the instruments.

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)

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Indications for Use

510(k) Number (if known)
K210637

Device Name
IPC Powerease™ Compatible CD Horizon™ Spinal System Instruments

Indications for Use (Describe)

The IPC™ System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC™ Powerease™ System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

Do not implant instruments.

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)

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510(k) SUMMARY

March 02, 2021

I. Company: Medtronic
1800 Pyramid Place
Memphis, TN 38132
Telephone Number: (901) 396-3133

Contact: Shweta Sharma
Principal Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: shweta.s.sharma@medtronic.com

Proprietary Trade Name: CD Horizon™ Spinal System

Common Name: Bone Screws

**Classification Name/
Regulation Numbers/
Classification/
Classification Product
Code/
Subsequent Product
Codes (if any)** CD Horizon™ Spinal System
Bone Screw, Pedicle Screw
Thoracolumbosacral Pedicle Screw System
Class II
888.3070

Implants: NKB, KWP, KWQ

Navigated Instruments
Orthopedic Stereotaxic Instrument
OLO, 882.4560, Class II

IPC™ POWEREASE™ System Instruments
Drills, Burrs, Trephines & Accessories (Simple, Powered)
HBE, 882.4310, Class II

II. Predicate Devices:

Primary Predicate:
CD Horizon™ Spinal System (K201407, S.E. 09/10/2020)

Additional Predicate:
CD Horizon™ Spinal System (K061591, S.E. 09/08/2006)
CD Horizon™ Spinal System (K042025, S.E. 08/25/2004)
CD Horizon™ Spinal System (K170679, S.E. 05/11/2017)
CD Horizon™ Spinal System (K113174, S.E. 11/21/2011)
CD Horizon™ Spinal System (K111520, S.E. 10/26/2011)
CD Horizon™ Spinal System (K140454, S.E. 05/22/2014)
CD Horizon™ Spinal System (K182121, S.E. 11/02/2018)
CD Horizon™ Spinal System (K203291, S.E. 12/08/2020)

CD Horizon™ Spinal System (K201362, S.E. 08/19/2020)
CD Horizon™ Spinal System (K203678, S.E. 01/15/2021)

These predicate devices have not been subject to a design-related recall.

III. Device Description:

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.

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.

*Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™
Powerease™ Systems*

Medtronic Navigated Reusable Instruments are spine preparation instruments made of high grade stainless steel. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allows a Medtronic computer-assisted surgery system such as the StealthStation™ Image Guidance System to track the instruments in the surgical field.

Medtronic Navigated Reusable Instruments are compatible with various Medtronic spinal implant systems. These instruments are also compatible with Medtronic's IPC™ Powerease™ System when connected to the Powerease™ Driver.

Medtronic Reusable Instruments for use with the IPC™ Powerease™ System

The Medtronic Reusable Instruments compatible with Medtronic's IPC™ Powerease™ System are spine preparation instruments, manufactured from materials commonly used in orthopedic procedures which meet available national or international standards specifications. Instruments may be connected to the Powerease™ Driver or used manually. These instruments are also compatible with various Medtronic spinal implant systems.

IV. Indications for Use:

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.

*Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™
Powerease™ Systems*

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic

surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC™ Powerease™ System.

Do not implant the instruments.

Medtronic Reusable Instruments for use with the IPC™ Powerease™ System

The IPC™ System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

The IPC™ Powerease™ System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in placement or cutting of screws, posts and rods.

Do not implant instruments.

V. Comparison of the Technological Characteristics with the Predicate Device:

The subject CD Horizon™ Spinal System devices have the same intended use, indications for use, similar overall design, sterilization, surgical procedure and materials as the following FDA primary and additional predicates cleared in K201407 (09/10/2020), K061591 (S.E. 09/08/2006), K042025 (S.E. 08/25/2004), K170679 (S.E. 05/11/2017), K113174 (S.E. 11/21/2011), K111520 (S.E. 10/26/2011), K140454 (S.E. 05/22/2014), K182121 (S.E. 11/02/2018), K203291 (S.E. 12/08/2020), K201362 (S.E. 08/19/2020) and K203678 (S.E. 01/15/2021). The predicate and subject implants and instruments have the identical function and fundamental scientific technology.

VI. Performance Data:

In accordance with the 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. The subject devices have been tested or rationalized based on if Medtronic believes that testing is not warranted for the subject devices as they do not present a new worst case when compared to the predicate devices. For subject devices that are rationalized, all existing predicate data previously provided in the predicate

510(k)s are still applicable. For subject devices that are tested have met the pre-determined acceptance criteria for all tests. The mechanical tests were performed per ASTM F1798 (Axial Grip, Axial Torsion, Flexion Extension Static, Flexion Extension Fatigue) and ASTM F1717 (Static Compression, Static Torsion, Compression Fatigue). Therefore, Medtronic believes design verification testing demonstrated that the subject devices are substantially equivalent to the predicate devices. Design validation testing has also been performed and demonstrated that the subject devices performed as intended.

VII. Conclusions

The subject CD Horizon™ Spinal System devices have shown through supporting information provided in this premarket notification to be substantially equivalent to the identified predicate devices.