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

August 19, 2020

Re: K201362
Trade/Device Name: CD Horizon™ Fenestrated Screw Set, CD Horizon™ Spinal System, Kyphon™ HV-R™ Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NDN, NKB, KWP, KWQ, OLO, HWE
Dated: May 21, 2020
Received: May 22, 2020

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,

for

Colin O'Neill, M.B.E.
Acting 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)*

K201362

Device Name
CD Horizon™ Fenestrated Screw Set

Indications for Use *(Describe)*
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.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201362

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K201362

Device Name
Kyphon™ HV-R™ Bone Cement

Indications for Use *(Describe)*

Kyphon™ HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathological fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/ or presence of a lytic lesion) without obvious loss of vertebral body height.

When used in conjunction with CD Horizon™ Fenestrated Screws, Kyphon™ HV-R™ Bone Cement is 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 are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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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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)*

K201362

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201362

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

Indications for Use *(Describe)*
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 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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510(k) SUMMARY

May 21, 2020

I. Company: Medtronic Sofamor Danek, USA Inc.
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™ Fenestrated Screw Set
CD Horizon™ Spinal System
Kyphon™ HV-R™ Bone Cement

Common Name: Bone Screw, Pedicle Screw, Cement

Classification Name/
Regulation Numbers/
Classification/
Classification Product
Code/
Subsequent Product
Codes (if any)

CD Horizon™ Fenestrated Screw Set
Bone Cement, Posterior Screw Augmentation
Class II
888.3027
PML

NKB, NDN
Orthosis, Pedicle Screw Fixation
Cement, Bone, Vertebroplasty
Thoracolumbosacral Pedicle Screw System
888.3070 and 888.3027

CD Horizon™ Spinal System
Bone Screw, Pedicle Screw
Thoracolumbosacral Pedicle Screw System
888.3070
NKB, HWE, KWP, KWQ, OLO

Kyphon™ HV-R™ Bone Cement
Bone Cement, Posterior Screw Augmentation
Cement, Bone, Vertebroplasty
888.3027
Class II
PML, NDN

II. Predicate Devices:

Primary Predicate:
CD Horizon™ Fenestrated Screw Set (K191148, S.E. 09/12/2019)

Additional Predicates:
CD Horizon™ Spinal System (K170679, S.E. 05/11/2017)
CD Horizon™ Spinal System (K122433, S.E. 03/22/2013)
CD Horizon™ Spinal System (K140454; S.E. 05/22/2014)
CD Horizon™ Spinal System (K042025, S.E. 08/25/2004)

Additional Predicates:
CD Horizon™ Fenestrated Screw Set (K152604, S.E. 01/06/2016)
CD Horizon™ Fenestrated Screw Set (K193011, S.E. 01/10/2020)
Kyphon™ HV-R™ Bone Cement (K180700, S.E. 05/18/2018)
Medtronic HV-R™ Fenestrated Screw Cement (K152604, S.E. 01/06/2016)

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

III. Device 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 (Kyphon™ HV-R™ Bone Cement or 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.

To achieve best results, do not use CD Horizon™ Fenestrated Screw implants with components from any system other than the CD Horizon™ Spinal System. As with all orthopedic and neurosurgical implants, CD Horizon™ Fenestrated Screw implants should never be reused under any circumstances.

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, 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.

Kyphon™ HV-R™ Bone Cement

Kyphon™ HV-R™ Bone Cement is a polymethylmethacrylate (PMMA) that contains approximately 30% barium sulfate. It is designed for delivery in a highly viscous state. Kyphon™ HV-R™ Fenestrated Screw Cement is provided sterile in two components: 20 grams of powder and nine grams of liquid. The powder contains methylmethacrylate-styrene co-polymer, barium sulfate, and benzoyl peroxide. The liquid contains methylmethacrylate (monomer), hydroquinone and N, N dimethyl-p-toluidine.

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. The 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™ 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, 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.

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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.

Kyphon™ HV-R™ Bone Cement

Kyphon™ HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathological fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

When used in conjunction with CD Horizon™ Fenestrated Screws, Kyphon™ HV-R™ Bone Cement is 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 are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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

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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
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 the instruments.

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

The primary predicate for the subject devices is CD Horizon™ Fenestrated Screw Set (K191148, S.E. 09/12/2019). The subject CD Horizon™ fenestrated screws have the same intended use, same or similar overall design, surgical technique, sterilization and materials as the following FDA primary predicate cleared in K191148, K170679 (S.E. 05/11/2017) and K122433 (S.E. 03/22/2013). The predicate and subject new fenestrated screws have the identical function and fundamental scientific fundamental technology.

The subject CD Horizon™ Spinal System devices have the same intended use, similar overall design, sterilization, surgical procedure and materials as the following FDA primary predicate cleared in K170679 (S.E. 05/11/2017), K122433 (S.E. 03/22/2013) and K140454 (S.E. 05/22/2014). The predicate and subject new implants and instruments have the identical function and fundamental scientific fundamental technology.

Modification made to the existing CD Horizon™ Fenestrated Screw Set to expand surgical procedural workflow is identical to predicate K170679 (S.E. 05/11/2017), K122433 (S.E. 03/22/2013), K140454 (S.E. 05/22/2014) and K124004 (S.E. 05/11/2107).

There are no technology changes to the existing CD Horizon™ Fenestrated Screw Set or Kyphon™ HV-R™ Bone Cement. However, the CD Horizon™ Fenestrated Screw Set system and Kyphon™ HV-R™ Bone Cement labeling has been updated to reflect use with each other. This intended use is same as the predicates Medtronic HV-R™ Bone Cement (K152604, S.E. 01/06/2016).

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 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 per ASTM F1798 (static axial grip, static axial torsion, static flexion extension, and dynamic flexion extension) and ASTM F1717 (static and dynamic compression bending and static torsion) have met the pre-determined acceptance criteria for all tests. Therefore, Medtronic believes design verification testing demonstrated that the subject devices are substantially equivalent to the predicate Medtronic screws. Design validation testing has also been performed and demonstrated that the subject devices performed as intended.

VII. Conclusions

The subject CD Horizon™ Fenestrated Screw Set devices, CD Horizon™ Spinal System devices and Kyphon™ HV-R™ Bone Cement have shown through supporting information provided in this premarket notification to be substantially equivalent to the identified predicate devices.