October 4, 2022

Medtronic Sofamor Danek USA, Inc.
Shana Foster
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K221646
Trade/Device Name: CD HORIZON™ ASTUTE™ SPINAL SYSTEM; CD HORIZON™ Growth Rod Conversion Set; CD HORIZON™ SPINAL SYSTEM; CD Horizon™ Fenestrated Screw Set; COLORADO 2™ SPINAL System; GDLH™ POSTERIOR SPINAL SYSTEM; SHILLA™ Growth Guidance System; TENOR™ SPINAL SYSTEM
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP, NQP, PGM
Dated: September 6, 2022
Received: September 12, 2022

Dear Shana Foster:

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.
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)*
K221646

Device Name
CD HORIZON™ ASTUTE™ Spinal System

Indications for Use *(Describe)*
CD Horizon™ Astute™ Spinal System
The CD Horizon™ Astute™ Spinal System is intended to provide for posterior, supplemental fixation when used with an interbody fusion cage for patients diagnosed with degenerative disc disease (DDD- defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). 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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221646

Device Name
CD Horizon™ Fenestrated Screw Set

Indications for Use *(Describe)*

CD Horizon™ Fenestrated Screws

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 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 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)

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221646

Device Name
CD HORIZON™ Growth Rod Conversion Set

Indications for Use *(Describe)*
CD Horizon™ Growth Rod Conversion Set
The CD Horizon™ Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency including early-onset scoliosis. The CD Horizon™ Growth Rod Conversion Set may be used with any cleared traditional CD Horizon™ Spinal System rod construct ranging in diameter from 3.5mm to 5.5mm, with the exception of PEEK Rod constructs. The CD Horizon™ Growth Rod Conversion Set may not be used with PEEK rods, Spire™ Spinous Process Plates, or Shape Memory Alloy (SMA) Staples.

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) Number *(if known)*
K221646

Device Name
CD HORIZON™ Spinal System

Indications for Use *(Describe)*

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, 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 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, 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.

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 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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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)*
K221646

Device Name
GDLH™ Posterior Spinal System

Indications for Use *(Describe)*
GDLH™ Posterior Spinal System
The GDLH™ Posterior Spinal System, when using TSRH™ variable angle screws, is intended only for patients (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) receiving fusions using autogenous bone graft only; (c) having the device fixed or attached to the lumbar and sacral spine: and (d) having the device removed after the development of a solid fusion mass.
When properly used, this system is intended to assist stabilization until a solid spinal fusion develops. Except for situations where screws are attached to the pedicles of the lumbar and sacral spine via a posterior surgical approach in a GDLH™ construct for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the L5-S1 vertebral joint, the specific indications for the GDLH™ Posterior Spinal System are the following:
- Degenerative disc disease (DDD - as defined by instability in the presence of one or more of the following: osteophyte formation, decrease in disc space height, endplate sclerosis, disc herniations, facet joint changes, and scarring and/or thickening of the annulus fibrosis, ligamentum flavum, or facet joint capsule).
- Pseudoarthrosis.
- Stenosis.
- Spondylolisthesis.
- Spinal deformities such as scoliosis, kyphosis, and lordosis.
- Fracture.
- Unsuccessful previous attempts at spinal fusion.
- Tumor resection.

Nota bene: the GDLH™ Posterior Spinal System is limited to non-cervical use. TSRH™ variable angle when used with the GDLH™ Posterior Spinal System, are intended for sacral/iliac attachment only. GDLH™ hooks and Crosslink™ bars are intended for posterior thoracic and/or lumbar use only.

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)*

K221646

Device Name
COLORADO 2™ Spinal System

Indications for Use *(Describe)*

Colorado 2™ Spinal System

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Colorado 2™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) pseudarthrosis.

In addition, when used as a pedicle screw fixation system, the Colorado 2™ Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5 S1) vertebral joint, (2) receiving fusions using autogenous bone graft only, (3) having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (4) having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the Colorado 2™ Spinal System is intended for the following indications: (1) degenerative disc disease (DDD - as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, and/or (7) tumor resection.

When used as an anterolateral thoracic/lumbar system, the Colorado 2™ Spinal System is intended for the following indications: (1) DDD (as defined by back pain of discogenic origin with degeneration of the disc confirmed b patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, and/or (7) tumor resection.

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221646

Device Name
SHILLA™ Growth Guidance System

Indications for Use *(Describe)*
Shilla™ Growth Guidance System
The Shilla™ Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome. The Shilla™ Growth Guidance System is intended to be removed after skeletal maturity.

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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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)*
K221646

Device Name
TENOR™ Spinal System

Indications for Use *(Describe)*
Tenor™ Spinal System
The Tenor™ Spinal System, when used for pedicle screw fixation, is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5-S1) vertebral joint; (b) receiving fusions using autogenous bone graft only; (c) having the device fixed to the lumbar and sacral spine (levels of pedicle screw fixation may be from L3 to sacrum); and (d) having the device removed after the development of a solid fusion mass.
Note: Tenor™ Plates are intended for the L5-S1 pedicle screw indication only.
The Tenor™ Spinal System, when used as a posterior, non-pedicle screw fixation system, is intended for the following indications:
- Degenerative disc disease (DDD - as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
- Pseudarthrosis.
- Stenosis.
- Spondylolisthesis.
- Spinal deformities such as scoliosis, kyphosis, and/or lordosis.
- Fracture.
- Tumor resection.

When used for posterior non-pedicle screw fixation, the Tenor™ Spinal System is intended for thoracic, lumbar, and sacral (T1– Sacrum) fixation only.

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
MEDTRONIC Sofamor Danek
MRI Update for Medtronic ThoracoLumboSacral Anterior & Posterior Spinal Fixation Systems
October 4, 2022

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person:	Shana Foster Regulatory Affairs Specialist
Date Prepared:	October 4, 2022
Name of Device:	**Medtronic ThoracoLumboSacral Anterior & Posterior Spinal Fixation Systems** 1. CD HORIZON™ ASTUTE™ SPINAL SYSTEM 2. CD HORIZON™ Growth Rod Conversion Set 3. CD HORIZON™ SPINAL SYSTEM 4. CD Horizon™ Fenestrated Screw Set; Applies to US only parts 5. COLORADO 2™ SPINAL System 6. GDLH™ POSTERIOR SPINAL SYSTEM 7. SHILLA™ Growth Guidance System 8. TENOR™ SPINAL SYSTEM
Common Name (with target population intended for MRI construct)	**CD HORIZON™ ASTUTE™ SPINAL SYSTEM**: Rods & Set Screws | **CD HORIZON™ Growth Rod Conversion Set**: Set Screws & Connectors | **CD HORIZON™ SPINAL SYSTEM**: Rods, Staples, Screws, Set Screws, Bolts, Connectors/Dominos, Hooks, Nut Caps, Plates, Sliders, Washers, Staples, Crosslinks, Rod Stoppers, Spacer, C-Rings, Nuts |

	CD Horizon™ Fenestrated Screw Set: Screws | **COLORADO 2™ SPINAL System**: Connectors, Crosslinks, Screws, Set Screws, Plates, Clamps, Dominos, Hooks, Nuts, Rods, Staples | **GDLH™ POSTERIOR SPINAL SYSTEM**: Connectors, Crosslinks, Rods, Hooks & Set Screws | **SHILLA™ Growth Guidance System**: Set Screws, Screws, Rods & Crosslinks | **TENOR™ SPINAL SYSTEM**: Clamps, Connectors, Hooks, Crosslinks, Nuts, Rods & Screws |
Regulatory Class, Regulation Number, Regulation Name and Device Product Code:	KWP, KWQ, NKB, NQP, PGM 1. 21 CFR 888.3050 | Device Class II | KWP - Appliance, Fixation, Spinal Interlaminal 2. 21 CFR 888.3060 | Device Class II | KWQ - Appliance, Fixation, Spinal Intervertebral Body) 3. 21 CFR 888.3070 | Device Class II | See indented list below: a. NKB - Thoracolumbosacral Pedicle Screw System b. NQP - Posterior Metal/Polymer Spinal System, Fusion c. PGM - Growing Rod System
Trade Name:	1. CD HORIZON™ ASTUTE™ SPINAL SYSTEM 2. CD HORIZON™ Growth Rod Conversion Set 3. CD HORIZON™ SPINAL SYSTEM 4. CD Horizon™ Fenestrated Screw Set; Applies to US only parts 5. COLORADO 2™ SPINAL System

	6. GDLH™ POSTERIOR SPINAL SYSTEM 7. SHILLA™ Growth Guidance System 8. TENOR™ SPINAL SYSTEM
Predicate Devices:	• **Primary Predicate 1**- K201407 CD Horizon™ Spinal System (S.E. 09/10/2020) • **Predicate 2**- K191066 CD HORIZON™ ASTUTE™ SPINAL SYSTEM (S.E. 10/03/2019) • **Predicate 3**- K150200 CD HORIZON Growth Rod Conversion Set (S.E. 02/25/2015) • **Predicate 4**- K201362 CD Horizon™ Fenestrated Screw Set, CD Horizon™ Spinal System, Kyphon™ HV-R™ Bone Cement (S.E. 08/19/2020) • **Predicate 5**- K030875 MODIFICATION TO COLORADO 2SPINAL SYSTEM (S. E. 06/24/2003) • **Predicate 6**- K954645 TITANIUM GDLH POSTERIOR SPINAL SYSTEM (S.E. 01/16/1996) • **Predicate 7**- K140750 SHILLA GROWTH GUIDANCE SYSTEM (S.E. 07/17/2014) • **Predicate 8**- K022191 MODIFICATION TO TENOR SPINAL SYSTEM (S.E. 08/28/2002)
Description of Devices:	**CD HORIZON™ ASTUTE™ SPINAL SYSTEM** The CD Horizon™ Astute™ Spinal System consists of a variety of sizes of rods, as well as set screws, which are used with bone screws from the CD Horizon™ Solera™ Spinal System, to create a variety of rigidly locked configurations, with each construct being tailored to the individual case. CD Horizon™ Astute™ Spinal System implant components are fabricated from medical grade titanium alloy, tantalum, or polyetheretherketone (PEEK). Medical grade titanium, titanium alloy, or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, or medical grade cobalt-chromium-molybdenum alloy with stainless

	steel in the same construct. Only use set screws designed for use with CD Horizon™ Astute™ rods. PEEK implants may be used with titanium alloy or cobalt-chromium-molybdenum alloy implants. CD Horizon™ Astute™ Spinal System rods are not to be used with Crosslink™ plates, fixed angle screws, sagittally adjusting screws, or in pediatric patients. To achieve best results, do not use CD Horizon™ Astute™ Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. **CD HORIZON™ Growth Rod Conversion Set** The CD Horizon™ Growth Rod Conversion Set consists of a variety of inline connectors used with certain CD Horizon™ Spinal System components to create posterior pedicle screw and hook constructs intended for treatment of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The CD Horizon™ Growth Rod Conversion Set is used with CD Horizon™ Spinal System rods (ranging in diameter from 3.5mm to 5.5mm), pedicle screws, hooks, and connectors of various sizes. These implants are used to form a distinct spinal construct in growing children to correct spinal deformities in a non-fusion manner. Similar to CD Horizon™ implants used in fusion cases, these components are rigidly locked into a variety of configurations with each construct being tailor-made for the individual. As the patient grows, subsequent lengthening surgeries are performed periodically to reapply tension/distraction to the construct. These surgeries are repeated until the child has reached skeletal maturity, at which point the implants may be removed. Certain components within the CD Horizon™ Spinal System are excluded for use in pediatric patients and, therefore, are excluded for use with the CD Horizon™ Growth Rod Conversion Set. These include PEEK rods, Shape Memory Alloy Staples and Spire™ Plates. All

	screws used in pediatric cases are only cleared for use via a posterior approach. CD Horizon™ Growth Rod Conversion Set components are fabricated from medical grade stainless steel or titanium alloy. Compatible CD Horizon™ Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy. 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. To achieve best results, do not use any of the CD Horizon™ Growth Rod Conversion Set implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. **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 3.5mm to 6.35mm), hooks, screws, Crosslink™ plates, and connecting components. Similar to the CD Horizon™ implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Certain components within the CD Horizon™ Spinal System are specifically excluded for use in pediatric patients. These include PEEK rods, Spire™ plates. Screws used in pediatric cases are only cleared for use via a

	posterior approach. All 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; Crosslink™ bar and connectors and Medtronic multi-axial rods and screws. Note that 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 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. 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. 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.

	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. To achieve best results, do not use CD Horizon™ Fenestrated Screw implants with components from any system other than the CD Horizon™ Spinal System. **COLORADO 2™ SPINAL System** The Colorado 2™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. Colorado 2™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Colorado 2™ Spinal System implant components are fabricated from medical grade stainless steel. Alternatively, the entire

	system may be fabricated from medical grade titanium or titanium alloy. The titanium version of the Colorado 2™ Spinal System is used in conjunction with GDLH™ φ5.5 rods, TSRH™ Spinal System rods and Tenor™ Spinal System rods. To achieve best results, do not use Colorado 2™ Spinal System implant components with components from any other system or manufacturer. Never use stainless steel and titanium implant components in the same construct. **GDLH™ POSTERIOR SPINAL SYSTEM** The GDLH™ Posterior Spinal System consists of a variety of shapes and sizes of rods, hooks, and connecting components. TSRH™ variable angle screws may also be used with the GDLH™ Posterior Spinal System. GDLH™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. GDLH™ Posterior Spinal System implant components are fabricated from medical grade stainless steel described by ASTM Standard F 138, Grade 2 (commonly called 316 LVM Stainless Steel) or ISO 5832-1 or ISO 5832-9. This material is not compatible with titanium, MP35N™1 or any other alloy. Alternatively, GDLH ™ Posterior Spinal System implant components are fabricated from titanium alloy (Ti-6Al-4V) such as described by ASTM F136 or ISO 5832-3. Implant components made from different metal alloys must not be used together in a construct. Medtronic expressly warrants these devices are fabricated from the foregoing material specifications. To achieve the best results, do not use GDLH™ Posterior Spinal System 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 implants, none of the GDLH Posterior Spinal System components should ever be reused under any circumstances. **SHILLA™ Growth Guidance System**

	The Shilla™ Growth Guidance System consists of stainless steel components used to form a distinct spinal construct in growing children. The Shilla™ Growth Guidance System set screw provides attachment of a spinal pedicle screw to a spinal rod. Unlike a typical set screw, which rigidly locks the vertical rod inside the connector housing to the pedicle screw, the Shilla™ Growth Guidance System set screw captures the rod within the screw housing, but does not fix it rigidly to the pedicle screw. The Shilla™ Growth Guidance System consists of a construct that includes 4.5mm or 5.5mm diameter rods, fixed angle and multi-axial screws, and Crosslink™ plates. Additionally, the construct may be supplemented with sublaminar wire. Shilla™ Growth Guidance System implants are provided non-sterile. Shilla™ Growth Guidance System implants are not to be used with implants from other systems. Never use stainless steel and titanium implant components in the same construct. **TENOR™ SPINAL SYSTEM** The Tenor™ Spinal System consists of a variety of shapes and sizes of rods, screws, bolts, clamps, connectors, plates, cross-connectors, washers, and nuts. The Tenor™ Spinal System may be used with GDLH™ 5.5mm rods, TSRH™ hooks and connectors, TSRH™ Low Profile Crosslink™ plates, CD Horizon™ Low Profile Multi-span™ Crosslink™ plates, and/or Multi-axial Low Profile Multi-span™ Crosslink™ plates for attachment to the posterior thoracic and lumbar spine. All screws/bolts in this system are 5.5mm in diameter or larger. Implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Tenor™ Spinal System implants are fabricated from medical grade titanium alloy. Alternatively, the entire system may be manufactured from medical grade stainless steel. Never use stainless steel and titanium implant components in the same construct. To achieve best results, do not use Tenor™ Spinal System implants with components from any other system or

	manufacturer unless specifically allowed to do so in this or another Medtronic document.
Indications for Use:	**CD HORIZON™ ASTUTE™ SPINAL SYSTEM** The CD Horizon™ Astute™ Spinal System is intended to provide for posterior, supplemental fixation when used with an interbody fusion cage for patients diagnosed with degenerative disc disease (DDD- defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). 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. **CD HORIZON™ Growth Rod Conversion Set** The CD Horizon™ Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency including early-onset scoliosis. The CD Horizon™ Growth Rod Conversion Set may be used with any cleared traditional CD Horizon™ Spinal System rod construct ranging in diameter from 3.5mm to 5.5mm, with the exception of PEEK Rod constructs. The CD Horizon™ Growth Rod Conversion Set may not be used with PEEK rods, Spire™ Spinous Process Plates, or Shape Memory Alloy (SMA) Staples. **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, 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 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, 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. 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 the Vertex™ indications of 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 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 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. **COLORADO 2™ SPINAL System** When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Colorado 2™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) pseudarthrosis. In addition, when used as a pedicle screw fixation system, the Colorado 2™ Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5 S1) vertebral joint, (2) receiving fusions using autogenous bone graft only, (3) having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (4) having the device removed after the development of a solid fusion mass. When used as a posterior, non-cervical, non-pedicle screw fixation system, the Colorado 2™ Spinal System is intended for the following indications: (1) degenerative disc disease (DDD - as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection. When used as an anterolateral thoracic/lumbar system, the Colorado 2™ Spinal System is intended for the following indications: (1) DDD (as defined by back pain of discogenic origin with degeneration of the disc confirmed b patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection. **GDLH™ POSTERIOR SPINAL SYSTEM**

	The GDLH™ Posterior Spinal System, when using TSRH™ variable angle screws is intended only for patients (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) receiving fusions using autogenous bone graft only; (c) having the device fixed or attached to the lumbar and sacral spine: and (d) having the device removed after the development of a solid fusion mass. When properly used, this system is intended to assist stabilization until a solid spinal fusion develops. Except for situations where screws are attached to the pedicles of the lumbar and sacral spine via a posterior surgical approach in a GDLH™ construct for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the L5-S1 vertebral joint, the specific indications for the GDLH™ Posterior Spinal System are the following: 1. Degenerative disc disease (DDD - as defined by instability in the presence of one or more of the following: osteophyte formation, decrease in disc space height, endplate sclerosis, disc herniations, facet joint changes, and scarring and/or thickening of the annulus fibrosis, ligamentum flavum, or facet joint capsule). 2. Pseudoarthrosis. 3. Stenosis. 4. Spondylolisthesis. 5. Spinal deformities such as scoliosis, kyphosis, and lordosis. 6. Fracture. 7. Unsuccessful previous attempts at spinal fusion. 8. Tumor resection. Nota bene: the GDLH™ Posterior Spinal System is limited to non-cervical use. TSRH™ variable angle when used with the GDLH™ Posterior Spinal System, are intended for sacral/iliac attachment only. GDLH™ hooks and Crosslink™ bars are intended for posterior thoracic and/or lumbar use only. **SHILLA™ Growth Guidance System** The Shilla™ Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require

	surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early-onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome. The Shilla™ Growth Guidance System is intended to be removed after skeletal maturity. **TENOR™ SPINAL SYSTEM** The Tenor™ Spinal System, when used for pedicle screw fixation, is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5-S1) vertebral joint; (b) receiving fusions using autogenous bone graft only; (c) having the device fixed to the lumbar and sacral spine (levels of pedicle screw fixation may be from L3 to sacrum); and (d) having the device removed after the development of a solid fusion mass. Note: Tenor™ Plates are intended for the L5-S1 pedicle screw indication only. The Tenor™ Spinal System, when used as a posterior, non-pedicle screw fixation system, is intended for the following indications: o Degenerative disc disease (DDD - as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). o Pseudarthrosis. o Stenosis. o Spondylolisthesis. o Spinal deformities such as scoliosis, kyphosis, and/or lordosis. o Fracture. o Tumor resection. When used for posterior non-pedicle screw fixation, the Tenor™ Spinal System is intended for thoracic, lumbar, and sacral (T1 – Sacrum) fixation only.
Comparison of Technological Characteristics with the Predicate Devices:	The subject devices do not differ from the technological characteristics of the predicate devices.
Performance Data:	The following performance data were provided in support of substantial equivalence:

	MRI Testing: In accordance with the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the subject Medtronic ThoracoLumboSacral Anterior & Posterior Spinal Fixation Systems were evaluated for MR-safety in accordance with the following standards: · **ASTM F2052:2015–** "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment" · **ASTM F2213:2017–** "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment" · **ASTM F2119:2007(Reapproved 2013)–** "Standard test method for evaluation of MR image artifacts from passive implants" · **ASTM F2182:2019^{e2}–** "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging" The Medtronic ThoracoLumboSacral Anterior & Posterior Spinal Fixation Systems have been labeled in accordance with **ASTM F2503** "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment". • FDA Guidance for Industry and FDA Staff "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" issued December 11, 2014 • FDA Guidance for Industry and FDA Staff "Assessment of Radiofrequency- Induced Heating in the Magnetic Resonance (MR) Environment for

	Multi-Configuration Passive Medical Devices" issued March 22, 2016 **Sterilization Testing:** Not applicable. Based on the supporting documentation provided in previous premarket notifications, the subject Medtronic ThoracoLumboSacral Anterior & Posterior Spinal Fixation Systems are as safe and effective.
Conclusion:	In this submission language in following sections is harmonized to ensure consistency between all 8 package inserts: Visual Inspection, Packaging, Cleaning & Sterilization, Cleaning & Decontamination, and Sterilization. These changes do not impact related specifications and therefore there is no need for further verification or validation testing