April 8, 2022

Medicrea International (Medtronic)
Ms. Karine Trogneux
Regulatory Affairs Manager
5389 Route de Strasbourg - Vancia
Rillieux-La-Pape, 69140
France

Re: K220724
Trade/Device Name: CD Horizon™ Spinal System and PASS LP™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: March 8, 2022
Received: March 14, 2022

Dear Ms. Trogneux:

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

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)*
K220724

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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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)*
K220724

Device Name
PASS LP™ spinal system

Indications for Use *(Describe)*
The PASS LP™ Spinal System is a pedicle screw fixation system intended for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (e.g., fracture or dislocation), deformity or curvature (e.g., scoliosis, kyphosis, and/or lordosis), tumor, spinal stenosis, pseudarthrosis, or failed previous fusion.
Except for rod plates and caps for sacral plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP™ Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. The PASS LP™ Spinal System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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

MEDICREA INTERNATIONAL

CD Horizon™ Spinal System and PASS LP™ Spinal System

Date Prepared: April 7th, 2022

I. Submitter and contact Person information		
Submitter	MEDICREA INTERNATIONAL (Medtronic) 5389 route de Strasbourg – Vancia RILLIEUX-LA-PAPE 69140 FR	
Contact Person	Karine Trogneux MEDICREA INTERNATIONAL (Medtronic) 5389 route de Strasbourg - Vancia RILLIEUX-LA-PAPE 69140 FR	
II. Subject Device Information		
Trade Name	CD Horizon™ Spinal System	
Regulatory Identification/ Classification	**Common Name:** **Product Codes:** **Regulation Number:** **Classification Name:** **Device Classification:**	Bone Fixation Appliance, Pedicle Screw NKB, KWP, KWQ 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System Class II
Trade Name	PASS LP™ Spinal System	
Regulatory Identification/ Classification	**Common Name:** **Product Codes:** **Regulation Number:** **Classification Name:** **Device Classification:**	Bone Fixation Appliance, Pedicle Screw NKB, KWP 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System Class II
III. Predicate and Reference Devices		
Primary Predicate Device	CD Horizon™ Spinal System (K113174, Cleared 11/21/2011) **Common Name:** **Product Codes:** **Regulation Number:** **Classification Name:**	 Bone Fixation Appliance, Pedicle Screw NKB, KWP, KWQ, MNH, MNI, OSH 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System
Additional predicate Devices	PASS LP™ Spinal System (K140738, Cleared 11/04/2014) **Common Name:** **Product Codes:** **Regulation Number:** **Classification Name:** CD Horizon™ Spinal System (K202771, Cleared 10/19/2020)	 Spinal Fixation Appliances MNI, MNH, KWP, OSH 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System

	Common Name:	Bone Fixation Appliance, Pedicle Screw
	Product Codes:	NKB, KWP, KWQ
	Regulation Number:	21 CFR 888.3070
	Classification Name:	Thoracolumbosacral Pedicle Screw System

IV. Description of Subject Device

The CD Horizon Spinal System and PASS LP™ Spinal System (including UNiD™ Patient Specific Rods) consist of a variety of shapes and size of rods, hooks, screws, crosslink, plates, staples and connecting components, as well as implants 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.

The purposes of this submission are to:

- Add the UNiD™ Patient Specific Rods (new diameter 4.75mm) to the previously cleared CD Horizon™ Spinal System (K113174, cleared 11/21/2011) and PASS LP™ Spinal System (K140738, cleared 11/04/2014)
- Change the propriety Trade Name from "PASS LP™ Patient Specific Rods" to "UNiD™ Patient Specific Rods"

UNiD™ Patient Specific Rods are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, or in cobalt chrome alloy Co-Cr28Mo6 conforming to ISO 5832-12 specifications and ASTM F1537 specifications.

UNiD™ Patient Specific Rods are differentiated in two subgroups: UNiD™ Patient Specific Standard Rods (UNiD ROD) and UNiD™ Patient Specific Percutaneous Rods (UNiD MIS). UNiD™ Patient Specific Rods have been designed and manufactured for one specific patient. UNiD™ Patient Specific Rods must be used during surgery for this patient only and must not be reused (single use only). The UNiD™ Patient Specific Rods 4.75 diameter rods are not compatible with the PASS LP system. For a complete guide to the system, it is important to refer to the surgical technique.

V. Indications for Use and Difference Explanation

Indication 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 PASS LP Spinal System The PASS LP™ spinal system is a pedicle screw fixation system intended for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (e.g., fracture or dislocation), deformity or curvature (e.g., scoliosis, kyphosis, and/or lordosis), tumor, spinal stenosis, pseudarthrosis, or failed previous fusion. Except for rod plates and caps for sacral plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP™ Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis and fracture caused by tumor and/or trauma. The PASS LP™ Spinal System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
VI. Comparison of Technological Characteristics with the Predicate Devices	
When the subject device UNiD™ Patient Specific Rods (including new diameter 4.75mm) is used with the CD Horizon Spinal System, they have the same fundamental scientific technology, indications for use, intended use, materials, and levels of attachment as the predicate CD Horizon™ Spinal System devices (K113174). The compatibility between the whole CD Horizon™ Spinal System and PASS LP™ Patient Specific Rods (Diameter 5.5mm and 6.0mm) is already cleared (K202771, Cleared. 10/19/2020).	

The difference between the predicate device CD Horizon™ rods (K113174, cleared 11/21/2011) and subject device is that rods used with the predicate CD Horizon™ Spinal System are cut and bent by the surgeon based on the need of the individual case, while the UNiD™ Patient Specific Rods are directly adapted to a unique patient by means of an industrial bending process prior to distribution for surgery. However, both the subject and predicate systems are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, or sacral spine.

In addition, the subject device UNiD™ Patient Specific Rods is directly adapted to a unique patient as the predicate device previously cleared PASS LP™ Spinal System (K140738, Cleared 11/04/2014).

VII. Performance Data (Non-Clinical Test Summary)

In accordance with the Guidance for Industry and FDA Staff – Spinal System 510(k)'s, Medicrea has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.

Static and dynamic compression bending and static torsion testing were conducted in accordance with ASTM F1717-18. This performance testing demonstrates mechanical equivalence of the subject UNiD™ Patient Specific Rods when used with the CD Horizon™ Spinal System.

Therefore, Medicrea believes that the testing confirmed that the subject devices are substantially equivalent to the predicates.

VIII. Conclusion

The UNiD™ Patient Specific Rods (including new Diameter 4.75mm) have shown through supporting information provided in this premarket notification to be substantially equivalent to the identified predicates.