Medicrea International SA
Karine Trogneux
Regulatory Affairs Manager
5389 Route De Strasbourg - Vancia
Rillieux-La-Pape, 69140
France

January 5, 2022

Re: K213281
Trade/Device Name: PASS LP™ Spinal System, CD Horizon™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: September 30, 2021
Received: October 1, 2021

Dear Karine 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,

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)*
K213281

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K213281

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.

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510(k) SUMMARY

Date Prepared: January 5, 2022

1. **Submitter:**

MEDICREA INTERNATIONAL (Medtronic)
5389 route de Strasbourg – Vancia
RILLIEUX-LA-PAPE 69140
FR

Contact Person:

Karine Trogneux
MEDICREA INTERNATIONAL
5389 route de Strasbourg - Vancia
RILLIEUX-LA-PAPE 69140
FR

2. **Trade name:** PASS LP™ Spinal System
CD Horizon™ Spinal System

Regulatory Identification/ Classification

PASS LP™ Spinal System
Thoracolumbosacral pedicle screw system
Regulation Number: 21CFR 888.3070
Product Code: NKB, KWP
Class II

CD Horizon™ Spinal System
Thoracolumbosacral pedicle screw system
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Product Code: NKB, KWP, KWQ
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**

Primary predicate for PASS LP™ Spinal System:

- PASS LP™ Spinal System (K080099, S.E. 09/04/2008)

Primary predicate for CD Horizon™ Spinal System

- CD Horizon™ Spinal System (K202771, S.E. 10/19/2021)

Additional predicate device:

- PASS LP™ Spinal System (K141398, S.E. 01/09/2015)
- PASS LP™ Spinal System (K190376, S.E. 05/02/2019)
- PASS LP™ Spinal System (K140738, S.E. 11/04/2014)
- CD Horizon™ Spinal System (K150178, S.E. 02/11/2015)
- CD Horizon™ Spinal System (K132471, S.E. 10/08/2013)

The predicates have not been subject to a design related recall.

4. **Description of the device:**

PASS LP™ Spinal System

The PASS LP™ Spinal System is composed of screws, hooks, rods, plates, cross links, connection and locking devices. The range of different sizes and shapes of the implants allows the surgeon to adapt to the pathology and morphology of each of his patients.

The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, with the exception of the rods intended for in situ bending which are manufactured in non-alloyed titanium (CP titanium) conforming to ISO 5832-2 specifications and ASTM F67 specifications.

CoCr rods and implants are manufactured in Cobalt-Chromium Molybdenum alloy Co-Cr28Mo6 conforming to ISO 5832-12 specifications and ASTM F1537 specifications. Under no circumstances are the implants reusable.

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.

The purpose of this submission following:

- introduce new PASS LP™ Spinal System 'Universal Crosslinks' components
- expand use of the previously cleared CD Horizon™ Spinal System rods with the subject PASS LP™ Universal Crosslinks
- expand use of previously cleared CD Horizon™ Spinal System hooks with previously cleared PASS LP™ Spinal System components

5. Indication for Use

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.

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.

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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.

6. Comparison of the Technological Characteristics with the Predicate Device

The subject PASS LP™ Spinal System 'Universal Crosslinks' components are technologically similar to the already cleared predicate PASS LP™ Spinal System components (K080099, K141398 and K190376) in terms of fundamental scientific technology, intended use, indication for use, material used and levels of attachment.

When subject PASS LP™ Universal Crosslink and the existing CD Horizon™ Spinal System components, are used together, there is no change to the fundamental scientific technology, indications for use, intended use, materials, and levels of attachment in comparison to the predicates CD Horizon™ Spinal System (K202771) and PASS LP™ Spinal System (K080099, K141398, K190376).

When existing PASS LP™ components and the existing CD Horizon™ Spinal System components, are used together, there is no change to the fundamental scientific technology, indications for use, intended use, materials, and levels of attachment in comparison to the predicates CD Horizon™ Spinal System (K202771, K150178, K132471) and PASS LP™ Spinal System (K141398, K190376).

7. 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.

Mechanical testing was conducted in accordance with ASTM F1717. The performance testing demonstrates mechanical equivalence of the subject PASS LP™ universal crosslinks when used with the CD Horizon™ 5.5/6.0 Spinal System.

The mechanical testing (e.g., dynamic compression bending) and an engineering analysis were performed to demonstrate substantial equivalence.

8. Conclusions

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