April 19, 2022

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

Re: K220810
Trade/Device Name: Infinity™ OCT System and PASS OCT Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: March 15, 2022
Received: March 21, 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)*
K220810

Device Name
Infinity™ OCT System

Indications for Use *(Describe)*
The Infinity™ OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3:

- Traumatic spinal fractures and/or traumatic dislocations.
- Instability or deformity.
- Failed previous fusions (e.g. pseudarthrosis).
- Tumors involving the cervical spine.
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Infinity™ OCT System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.
The Infinity™ OCT System may be used with PASS OCT Patient Specific UNiD OCT Rods. In order to achieve additional levels of fixation, the Infinity™ OCT System may be connected to the CD Horizon™ Spinal System and Vertex™ Reconstruction System rods with the Infinity™ OCT System rod connectors. Transition rods with differing diameters may also be used to connect the Infinity™ OCT System to the CD Horizon™ Spinal System. Refer to the CD Horizon™ Spinal System package insert and Vertex™ Reconstruction System package insert for a list of the indications of use.
Note: The 3.0mm multi axial screw (MAS) requires the use of MAS Crosslink™ at each level in which the 3.0mm screw is intended to be used.
The lateral offset connectors and MAS extension connectors are intended to be used with 3.5mm and larger diameter multi axial screws. The lateral offset connectors and MAS extension connectors are not intended to be used with 3.0mm screws.
Note: Segmental fixation is recommended for these constructs.

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.

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)*
K220810

Device Name
PASS OCT Spinal System

Indications for Use *(Describe)*
The PASS OCT spinal system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The PASS OCT spinal system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the PASS OCT spinal system may be connected to the PASS LP spinal system with the dual diameter rods. Refer to the PASS LP spinal system package insert for a list of the PASS LP spinal system 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

MEDICREA INTERNATIONAL S.A.
Infinity™ OCT System and PASS OCT Spinal System

Date Prepared: April 15, 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 S.A. (Medtronic) 5389 route de Strasbourg - Vancia RILLIEUX-LA-PAPE 69140 FR Phone: 00 33 4 69 85 95 39
II. Subject Device Information	
Device Name	Infinity™ OCT System and PASS OCT Spinal System
Regulatory Identification/ Classification	**Product Codes:** NKG **Common Name:** Posterior Cervical Screw System **Regulation Number:** 21 CFR§ 888.3075 **Classification Name:** Posterior Cervical Screw System **Device Classification:** Class II
III. Predicate and Reference Devices	
Primary Predicate Device	Infinity™ OCT System (K163375; cleared the 08/21/2017) **Product Codes:** NKG **Regulation Number:** 21 CFR 888.3075 **Classification Name:** Posterior Cervical Screw System
Additional Predicate devices	PASS OCT Patient Specific Rods (K153169; cleared the 01/29/2016) **Product Codes:** NKG **Regulation Number:** 21 CFR 888.3075 **Classification Name:** Posterior Cervical Screw System Infinity™ OCT System, PASS OCT Spinal System (K210449; cleared the 03/18/2021) **Product Codes:** NKG **Regulation Number:** 21 CFR 888.3075 **Classification Name:** Posterior Cervical Screw System
Reference Device	CD Horizon™ Spinal System (K113174; cleared the 11/21/2011) **Product Codes:** NKB **Regulation Number:** 21 CFR 888.3070 **Classification Name:** Thoracolumbosacral Pedicle Screw System

IV. Description of Subject Device

The Infinity™ OCT System and PASS OCT Spinal System (including UNID™ OCT Patient-Specific Rods) are posterior systems, which consist of a variety of shapes and sizes of rods, hooks, polyaxial screws, occipital plates, occipital bone screws, and connection components, which can be rigidly locked to the rod in a variety of configurations.

The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, Cobalt-chromium molybdenum alloy Co-Cr28Mo6 according to ISO 5832-12 and ASTM F1537.

The purpose of this submission is to add titanium alloy and cobalt chrome 3.5/4.75 mm transition rods to the line of UNID™ OCT Patient-Specific Rods. The subject rods are designed and manufactured for one specific patient and are compatible with Infinity™ OCT System and PASS OCT Spinal Systems (cranially) and the CD Horizon Spinal System (caudally). The UNID™ OCT Patient-Specific Rods must be used during surgery for this patient only and must not be reused (single use only).

V. Indications for Use

Infinity™ OCT System

The Infinity™ OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3:

- Traumatic spinal fractures and/or traumatic dislocations.
- Instability or deformity.
- Failed previous fusions (e.g. pseudarthrosis).
- Tumors involving the cervical spine.
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Infinity™ OCT System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Infinity™ OCT System may be used with PASS OCT Patient Specific UNiD OCT Rods. In order to achieve additional levels of fixation, the Infinity™ OCT System may be connected to the CD Horizon™ Spinal System and Vertex™ Reconstruction System rods with the Infinity™ OCT System rod connectors. Transition rods with differing diameters may also be used to connect the Infinity™ OCT System to the CD Horizon™ Spinal System. Refer to the CD Horizon™ Spinal System package insert and Vertex™ Reconstruction System package insert for a list of the indications of use.

Note: The 3.0mm multi axial screw (MAS) requires the use of MAS Crosslink™ at each level in which the 3.0mm screw is intended to be used.

The lateral offset connectors and MAS extension connectors are intended to be used with 3.5mm and larger diameter multi axial screws. The lateral offset connectors and MAS extension connectors are not intended to be used with 3.0mm screws.

Note: Segmental fixation is recommended for these constructs.

PASS OCT spinal system

The PASS OCT spinal system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic

dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including
intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The PASS OCT spinal system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.
In order to achieve additional levels of fixation, the PASS OCT spinal system may be connected to the PASS LP spinal system with the dual diameter rods. Refer to the PASS LP spinal system package insert for a list of the PASS LP spinal system indications of use.

VI. Comparison of Technological Characteristics with the Predicate and Reference Devices

The subject UNiD™ OCT Patient Specific Rods do not change to the fundamental scientific technology, indications for use, intended use, materials, and levels of attachment as compared to previously cleared UNiD™ OCT Patient Specific Rods. The subject and predicate UNiD™ OCT Patient Specific Rods are directly adapted to a unique patient by means of an industrial bending prior to surgery, which differ from the other rods in the Infinity™ OCT System and the PASS OCT Spinal System which are cut and bent by the surgeon based on the need of the individual case.

The compatibility between the Infinity™ OCT System and 3.5 mm section of the subject UNiD™ OCT Patient Specific Rods has been previously established in K210449.The compatibility between the CD Horizon Spinal System and the 4.75 mm section of the subject UNiD™ OCT Patient Specific Rods has been previously established in K220724.

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.
Rationales were provided confirming that the use of the UNID™ OCT patient specific Rods did not introduce a new worst case compared to the predicate Infinity™ OCT Rods. However, to confirm the compatibility of the caudal 4.75 mm portion of the subject rods with the CD Horizon Spinal System, the following tests were performed per ASTM F1717: static and dynamic compression bending, and static torsion.

VIII. Conclusion

Based on the test results and supporting information provided in this premarket notification, the subject 3.5/4.75 mm UNID™ OCT Patient Specific Rods are substantially equivalent to the identified predicate devices