DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medicrea International
Mr. David Ryan
VP, Product Development and Marketing
14 Porte du Grand Lyon
01700 Neyron
FRANCE

January 29, 2016

Re: K153169
Trade/Device Name: PASS OCT Patient Specific Rods
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: October 30, 2015
Received: November 2, 2015

Dear Mr. Ryan:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153169

Device Name
PASS OCT Patient Specific Rods

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 PASS OCT Patient Specific Rods

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted to add the ranges of Patient Specific Rods to PASS OCT Spinal System.

Date Prepared: 30 October 2015

1. **Submitter:**

MEDICREA INTERNATIONAL
14 Porte du Grand Lyon
NEYRON 01700

Contact Person:

David RYAN
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14 Porte du Grand Lyon
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2. **Trade name:** PASS OCT Patient Specific Rods

Regulatory Identification/Classification:

Orthosis, Cervical Pedicle Screw Spinal Fixation
Product Code: NKG
Unclassified, Pre-Amendment

Spinal Interlaminal Fixation Orthosis
Regulation Number: 21CFR 888.3050
Product Code: KWP
Class II

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

Primary predicate:

- PASS OCT Spinal System, (MEDICREA INTERNATIONAL, K150918)

No recall recorded for this product.

Reference Device:

- PASS LP Spinal System - Patient Specific Rods, (MEDICREA INTERNATIONAL, K140738)

4. **Description of the device:**

The PASS OCT Spinal System is a posterior system, which consists 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. See package insert of the system for labeling limitations.

The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, in PEEK OPTIMA LT1 conforming to ASTM F2026 specifications and in cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537 specifications, and also CP Titanium according to ASTM F67 and ISO 5832-2 specifications.

Function: The PASS OCT spinal system was developed as an implant:
- To provide immobilization and stabilization of posterior spinal segments
- to augment the development of a solid spinal fusion
- to provide stability to ease fusion
- to be mechanically resistant to allow the fusion of the operated level

The purpose of this submission is to add Patient Specific, UNiD OCT rods. The Patient Specific Rod is a rod bent before surgery by MEDICREA, following the design defined by the surgeon only specific to a unique patient.

5. Indication for Use

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 rods 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.

6. Substantial equivalence claimed to predicate devices

The PASS OCT Patient Specific Rods are technologically similar to the already cleared PASS OCT Spinal System Rods in terms of intended use, materials used, mechanical safety and performances

The table below compares the features and characteristics of PASS OCT components to their predicate devices.

Device	MEDICREA INTERNATIONAL (subject device)	MEDICREA INTERNATIONAL PASS OCT Spinal System
510(k) number	Unknown	K150918
Intended use		
Occipital	Yes	Yes
Cervical	Yes	Yes
Thoracic	Yes	Yes
Components		
Anchorage means	-Polyaxial screws - Polyaxial hooks - Occipital bone screws	-Polyaxial screws - Polyaxial hooks - Occipital bone screws
Rods diameter	Ø3.5 mm	Ø3.5 mm
Dual Diameter Rods	Ø3.5mm/ Ø5.5mm Ø3.5mm/ Ø6.0 mm	Ø3.5mm/ Ø5.5mm Ø3.5mm/ Ø6.0 mm
Straight rods	No	Yes
Pre-bent rods	No	Yes

Patient Specific Rods, pre-bent before surgery	Yes	No

Device	MEDICREA INTERNATIONAL (subject device)	MEDICREA INTERNATIONAL PASS OCT Spinal System
Materials		
	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3 -Grade Titanium according to ASTM F67-13 & ISO 5832-2 PEEK OPTIMA LT1 conforming to ASTM F2026 Co-Cr 28Mo6 alloy 1 (following the ASTMF1537	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3 -Grade Titanium according to ASTM F67-13 & ISO 5832-2 PEEK OPTIMA LT1 conforming to ASTM F2026 Co-Cr 28Mo6 alloy 1 (following the ASTMF1537

7. Non-clinical Test Summary:

The components of the PASS OCT Patient Specific Rods were mechanically evaluated in static and dynamic compression and static and dynamic torsion tests following the ASTM F2706-08. Each time, the mechanical test was conducted on a justified worst case.

8. Clinical Test Summary

Published literature was used to demonstrate substantial equivalence

9. Conclusions Non clinical and Clinical

The PASS OCT Patient Specific Rods components are substantially equivalent to legally marketed predicate device.