DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 11, 2016

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

Re: K161149
Trade/Device Name: PASS OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: June 23, 2016
Received: June 27, 2016

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)*
K161149

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 rods with the dual diameter rods or dominos. 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 additional components

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the PASS OCT Spinal System- Additional Components:

Date Prepared: 20 June 2016

1. **Submitter:**

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Contact Person :

David RYAN
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2. **Trade name:** PASS OCT Spinal System

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)

Additional predicate:

- Vertex Reconstruction System, (MEDTRONIC SOFAMOR DANEK USA; K143471)

No reference devices were used in this submission.

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.

Never use stainless steel and titanium implant components in the same construct.

To achieve best results, do not use any of the PASS OCT Spinal System implant components with components from any other systems or manufacturer unless specifically labeled to do so in this or another MEDICREA® INTERNATIONAL document.

MATERIALS: Titanium Alloy (Ti-6Al-4V) according to the ASTM F136-11 & ISO 5832-30; CP Titanium according to the ASTM F67 and ISO 5832-2; PEEK OPTIMA LT1® according to the ASTM F2026-10 and cobalt-chromium molybdenum alloy Co-Cr28Mo6 according to ISO5832-12 and ASTM F1537.

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 510(k) submission is to add offset connectors to the PASS OCT Spinal System.

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 or dominos. 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 Spinal system components are technologically similar to the already cleared PASS OCT Spinal System Components and Vertex Reconstruction System Components in terms of intended use, materials used, mechanical safety and performances

- PASS OCT Spinal System, (MEDICREA INTERNATIONAL, K150918)
- Vertex Reconstruction System, (MEDTRONIC SOFAMOR DANEK USA; K143471)

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

Device	MEDICREA INTERNATIONAL PASS OCT Spinal System NEW COMPONENT	MEDICREA INTERNATIONAL PASS OCT Spinal System	MEDTRONIC SOFAMOR DANEK Vertex Reconstruction System
510(k) number	Unknown	K150918	K143471
Intended use			
Occipital	Yes	Yes	Yes
Cervical	Yes	Yes	Yes
Thoracic	Yes	Yes	Yes
Components			
Anchorage means	-Polyaxial screws - Polyaxial hooks - Occipital bone screws	-Polyaxial screws - Polyaxial hooks - Occipital bone screws	- Multi-axial screws - Hooks - Occipital bone screws
Offset Connector	Yes	No	Yes
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	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3 - Grade Titanium according to ASTM F67 & ISO 5832-2 - Shape Memory Alloy (Nitinol-NiTi) according to ASTM F2063

7. Non-clinical Test Summary:

The subject components of the PASS OCT spinal were mechanically evaluated in axial and torsional grip and dynamic flexion-extension per ASTM F1798.

Pyrogenicity testing was conducted in support to PASS OCT component substantial equivalence.

8. Clinical Test Summary

No clinical data was provided.

9. Conclusions Non clinical and Clinical

The PASS OCT Spinal system components are substantially equivalent to legally marketed predicate device.