DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 25, 2017

Medicrea® International S.A.
David Ryan
VP Product Development and Marketing
14 Porte Du Grand Lyon
Neyron, 01700
France

Re: K162786
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: September 26, 2016
Received: October 3, 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 Part 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,

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)*
K162786

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, 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.

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510(K) SUMMARY

1. DEVICE SUBMITTER

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Contact Person:
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VP Product Development and Marketing
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Date Prepared: 01/13/2017

2. DEVICE

Name of Device: PASS LP Spinal System

Common or Usual Name: Top Loading Hooks System

Classification Name:

- ✓ Orthosis, Thoracolumbosacral pedicle screw system per NKB 888.3070
- ✓ appliance, fixation, spinal interlaminal per KWP 888.3050

Regulatory Class: II

Classification Product Code: NKB

Subsequent Product Code: KWP

3. PREDICATE DEVICE

Primary Predicate:

- ✓ PASS LP Spinal System, MEDICREA INTERNATIONAL, K161627 (primary)

This predicate has not-been subject to a design-related recall.

- ✓ APEX Spine System, SPINECRAFT, K132603 (reference device)
- ✓ ASTRA Spine System, SPINECRAFT, K150417 (additional predicate device)

4. DEVICE DESCRIPTION

The PASS LP Spinal System is designed to contribute to correction and surgical stabilization of the thoracic, lumbar and sacral spine.

The system consists of pedicle screws, hooks, sacral plates, iliac screws, connectors, clamps, rods, nuts, rod plates and crosslink components. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ISO 5832-3 ASTM F136 and cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

A subset of PASS LP Spinal System components may be used for posterior pedicle screw fixation in pediatrics cases. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, sacral plates, iliac screws, connectors, clamps, nuts and crosslink components. The PASS LP components can be rigidly locked into a variety of configurations, with each construct being tailored made for the individual case.

The purpose of this submission is to extend the PASS LP Spinal System, with the addition of new components:

- 'Top loading Pedicle hooks'
- 'Top loading Transverse Process hooks'

5. INDICATIONS FOR USE

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, 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.

The Indications For Use statement for the PASS LP Spinal System is identical to the predicate device. Both the subject and predicate device have the same intended use for the treatment of acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the features and characteristics of the PASS LP Spinal System to its predicate device. The design features, materials and dimensions were found to be substantially equivalent to these systems.

Table 1: Comparison of Technological Characteristics

Device	**PASS LP Spinal System, MEDICREA – New Components**	**PASS LP Spinal System, MEDICREA**	**APEX Spine System, SPINECRAFT**	**ASTRA Spine System, SPINECRAFT**
510(k) number		K161627	K132603	K150417
Intended use				
Thoracic, Lumbar spine	Yes	Yes	Yes	Yes
Posterior Approach	Yes	Yes	Yes	Yes
Design				
Laminar Hooks	No	Yes	Yes	Yes
Wide Laminar Hooks	No	No	Yes	Yes
Thoracic Hooks	Yes	Yes	No	Yes
Bifid / Pedicle Hooks	Yes	Yes	Yes	No
Offset Hooks	No	Yes	Yes	Yes
Color Coded	Color-coded anodizing of the implant to differentiate throat height and offsets	Color-code on the screw shank. Identical to differentiate blade length and offsets	Color-coded anodizing of the implant to differentiate throat height and offsets	Color-coded anodizing of the implant to differentiate throat height and offsets
Polyaxial Range of Motion *(if applicable)*	No polyaxial hooks	+/-12° (+/-1°)	No polyaxial hooks	No polyaxial hooks
Compatibility with rods	Ø5.5 mm and Ø6.0 mm	Ø5.5 mm and Ø6.0 mm	Ø5.5 mm and Ø6.0 mm	Ø5.5 mm and Ø6.0 mm
Torque-calibrated breakable set-screw	Yes	Yes	No	No

Device	PASS LP Spinal System, MEDICREA – New Components	PASS LP Spinal System, MEDICREA	APEX Spine System, SPINECRAFT	ASTRA Spine System, SPINECRAFT
Materials				
Components	Titanium alloy (Ti-6Al-4V ELI, following standards ASTM F136 and ISO 5832-3).	Titanium alloy (Ti-6Al-4V ELI, following standards ASTM F136 and ISO 5832-3). Cobalt Chrome alloy (CoCr28Mo, following standards ASTM F1537 and ISO 5832-12)	Manufactured from biocompatible: Titanium alloy (Ti-6Al-4V ELI, following standards ASTM F136)	Manufactured from biocompatible: Titanium alloy (Ti-6Al-4V ELI, following standards ASTM F136)

Material composition is identical to other MEDICREA® INTERNATIONAL products or SPINECRAFT Spine Systems that have been cleared via the 510(k) process.

7. PERFORMANCE DATA

Biocompatibility Testing

The biocompatibility evaluation for the PASS LP system was conducted in accordance with the FDA blue book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- ✓ Cytotoxicity
- ✓ Sensitization
- ✓ Irritation
- ✓ Systemic toxicity
- ✓ Pyrogen Testing

According to the standard **ISO 10993-1**, the PASS LP Spinal System is defined as implantable device in contact with tissue and bone and as a permanent contact with the patient.

For chemical composition, the material conforms toTi-6Al-4V ELI, following standards ASTM F136 and ISO 5832-3.

Mechanical testing

Following a preliminary Finite Element Analysis for the comparison of mechanical performances of predicate devices to the PASS LP new components, mechanical testing was assessed to be unnecessary to demonstrate substantial equivalence of the additional components' substantial equivalence in mechanical performance.

Finite Element Analysis

Finite Element Analysis was used to perform a thorough side-by-side comparison between additional components of the PASS LP system and predicate devices. Load cases were investigated based on static testing methods per ASTM F1798.

Clinical study

No clinical studies were performed.

Animal study

No animal studies were performed.

8. CONCLUSION

MEDICREA® INTERNATIONAL S.A. PASS LP Spinal System is substantially equivalent to its predicate device in terms of indications for use, design, material and function.