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

September 23, 2016

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

Re: K160640
Trade/Device Name: PASS XS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH
Dated: August 29, 2016
Received: August 30, 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,

Vincent J. Devlin -S

for
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)*
K160640

Device Name
PASS XS Spinal System

Indications for Use *(Describe)*
The PASS XS 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, pseudoarthrosis, or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS XS Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS XS 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.

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510(K) SUMMARY

DEVICE SUBMITTER

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Date Prepared: 09/21/2016

DEVICE

Name of Device: PASS XS Spinal System

Common or Usual Name: Pediatric Thoracolumbar Fixation System

Classification Name: Pedicle Screw Spinal System (21 CFR 888.3070)

Regulatory Class: III

Product Code: NKB, OSH, MNI, MNH

PREDICATE DEVICES

Medicrea Pass LP Spinal System, K141398 (primary).
Synthes Spine USS Small Stature Spinal System, K994121 (additional).
Globus Medical Revere 4.5 Spinal Stabilization System, K113395 (additional).
Depuy Moss Miami SS System, K964024 (additional).

DEVICE DESCRIPTION

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

The system consists of pedicle screws, connectors, rods, nuts, 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 ASTM F136 and ISO5832-3 and cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

The PASS XS components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The purpose of this submission is to introduce the PASS XS Spinal System which is, essentially, a smaller version of the PASS-LP system.

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INDICATIONS FOR USE

The PASS XS 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, pseudoarthrosis, or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS XS Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS XS Spinal System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The PASS XS Spinal System and the PASS LP Spinal System (K141398, primary) have the same technological characteristics and principles of operation. The PASS XS Spinal System and the USS Small Stature Spinal System (K994121, reference) have the same intended use and more restrictive indications for use. The PASS XS Spinal System and the Globus Medical Revere 4.5 Spinal Stabilization System (K113395, reference) have the same intended use and similar indications for use, and share similar key implant dimensions. Performance testing has demonstrated comparable safety and performance to Medicrea PASS LP Spinal System (K141398, primary) and Depuy Moss Miami SS System (K964024, reference). Thus, the PASS XS Spinal System is substantially equivalent to the PASS LP Spinal System (K141398, primary).

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The PASS XS Spinal System implants are made from the same materials as their predicates.

Mechanical testing

The tests performed on the PASS XS Spinal System (static axial compression, static torsion and dynamic axial compression according to ASTM F1717, and axial gripping, torsional gripping and flexion-extension according to ASTM F1798) indicate that the product is as mechanically sound as other devices commercially available.

Animal study

No animal studies were performed.

Clinical study

No clinical studies were performed.

CONCLUSION

The Medicrea PASS XS Spinal System is substantially equivalent to its predicate devices in terms of indications for use, design, material and function.