October 18, 2018

Astura Medical, LLC
Mr. Parker Kelch
Quality Manager
3186 Lionshead Avenue, Suite 100
Carlsbad, California 92010

Re: K182239
Trade/Device Name: OLYMPIC Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, OLO
Dated: August 17, 2018
Received: August 20, 2018

Dear Mr. Kelch:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S for MNM

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182240

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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V. 510(K) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

a. DEVICE SUBMITTER

MEDICREA® INTERNATIONAL S.A.
5389, route de Strasbourg
69140 RILLIEUX-LA-PAPE - France

Phone: +33 4 72 01 87 87
Fax: +33 4 72 01 87 88

Contact Person:
David RYAN
VP Product Development and Marketing
dryan@medicrea.com

Date Prepared: 08/16/2018

b. DEVICE

Name of Device: PASS LP Spinal System
Common or Usual Name: Spinal Fixation System
Classification Name:

✓ Thoracolumbosacral pedicle screw system per NKB 888.3070

Regulatory Class: II
Product Code: NKB, KWP

c. PREDICATE DEVICE

Xia® 3 Spinal System, K170496 (Primary)

EXPEDIUM® Spine System, K102249 (Additional)

PASS LP Spinal System, K162786 (Additional)

d. DEVICE DESCRIPTION

The PASS LP 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, 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 ASTM F136 or cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

A subset of PASS LP 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, 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 to the PASS LP, with the addition of new components: 'Dominoes & Iliac Connectors'.

e. 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.

f. 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.

Device	Stryker Corporation Xia® 3 Spinal System	DePuy Spine Inc. EXPEDIUM® Spine System	Medicrea® International PASS LP Spinal System	Medicrea® International PASS LP Spinal System 'Dominoes & Iliac Connectors'
510(k) number	K170496	K102249	K162786	To be determined
Intended use	Immobilization and stabilization of spinal segments in skeletally mature or pediatric patients	Immobilization and stabilization of spinal segments in skeletally mature or pediatric patients	Immobilization and stabilization of spinal segments in skeletally mature or pediatric patients	Immobilization and stabilization of spinal segments in skeletally mature or pediatric patients
Components				
Implants	- Dominoes - Iliac Connectors	- Dominoes - Iliac Connectors	- Dominoes - Iliac Connectors	- Dominoes - Iliac Connectors
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI

g. PERFORMANCE DATA

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

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
- ü Sensitization
- ü 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

According to the ASTM F1717-15, static axial compression, static torsion and dynamic axial compression tests have been performed on the new components and indicate that the products are substantially equivalent as other devices commercially available.

Clinical study
No clinical studies were performed.

Animal study
No animal studies were performed.

h. CONCLUSION

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