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 2, 2016

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

Re: K160698
Trade/Device Name: LigaPASS
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: August 8, 2016
Received: August 10, 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" (21CFR 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

IV. STATEMENT OF INDICATIONS FOR USE

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)*
K160698

Device Name
LigaPASS

Indications for Use *(Describe)*
The LigaPASS is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, and kyphosis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;

The LigaPASS system may also be used in conjunction with other medical implant grade implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of other implants.

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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Contact Person:
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Date Prepared: 08/08/2016

DEVICE

Name of Device: LigaPASS
Common or Usual Name: Bone Fixation Cerclage, Sublaminar
Classification Name: 888.3010 - Bone Fixation Cerclage
Regulatory Class: II
Product Code: OWI

PREDICATE DEVICES

Medicrea LigaPass, K132395.

Zimmer Spine Universal Clamp, K142053 (primary).

DEVICE DESCRIPTION

The LigaPASS System connects a rod to a vertebral body using a specific type of connector and a flexible band. This connector can independently tighten the rod and the bone anchor. It is comprised by a connector body, a rod set screw, a locking set screw for the band and a polyester band. Components in this connector are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136, pure titanium that conforms to ASTM F67 and Polyethylene Terephthalate (PET).

The purpose of this submission is 1) to introduce the LigaPASS 2.0 XS Connector which accommodates a 4.5mm rod and 2) to modify the LigaPASS indications to align with those of its primary predicate.

MEDICREA

INDICATIONS FOR USE

The LigaPASS is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, and kyphosis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;

The LigaPASS system may also be used in conjunction with other medical implant grade implants made of titanium or cobalt chrome alloy whenever “wiring” may help secure the attachment of other implants.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The LigaPASS 2.0 XS connector is technologically equivalent to the Medicrea LigaPass (K132395) and mechanically to the Zimmer Spine Universal Clamp (K142053).
The LigaPASS 2.0 XS connector has the same intended use and similar indications for use as both of these systems. Performance testing has demonstrated comparable safety and performance to the cleared posterior fixation device. Thus, the LigaPASS 2.0 XS connector is substantially equivalent to the Zimmer Spine Universal Clamp (K142053).

PERFORMANCE DATA

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

Biocompatibility Testing

The LigaPASS 2.0 XS is made from the same materials as its predicates.

Mechanical testing

The tests performed on the LigaPASS 2.0 XS connector (axial and torsional grip, and static and dynamic band tension 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 LigaPASS System is substantially equivalent to its predicate systems in terms of indications for use, design, material and function.