DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 30, 2017

Medicrea International S.A.
Mr. David Ryan
VP Product Development and Marketing
5389 route de Strasbourg – Vancia
Rillieux-La-Pape, 69140
France

Re: K172021
Trade/Device Name: LigaPASS
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: June 30, 2017
Received: July 5, 2017

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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172021

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 a 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
MEDICREA INTERNATIONAL's LigaPASS additional components

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

Date Prepared: August 29th 2017

1. **Submitter:**

MEDICREA INTERNATIONAL S.A.
5389 route de Strasbourg –
Vancia RILLIEUX-LA-PAPE 69140
FR

Contact Person:

David RYAN
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2. **Trade name:** LigaPASS

Regulatory Identification/ Classification

Bone fixation cerclage
Regulation Number : 21 CFR 888.3010
Product Code: OWI
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**

Primary predicate device:

- LigaPASS, (MEDICREA INTERNATIONAL, K160698)

Reference device:

- PASS LP Spinal System, (MEDICREA INTERNATIONAL, K100297)

4. **Description of the device:**

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.
The purpose of this submission is 1) to introduce the LigaPASS 2.0 Medial Connector and 2) to introduce the LigaPASS 2.0 Medial Open Connector.

MATERIALS: 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).

Function: The LigaPASS spinal system was developed as an implant:

- To provide temporary stabilization as bone anchor during the development of solid bony fusion.
- To aid the repair of bone fracture.

5. Indication 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.

6. Substantial equivalence claimed to predicate devices

The LigaPASS 2.0 Medial Connector components are technologically similar to the already cleared LigaPASS 2.0 LP Connector in terms of intended use, material used, mechanical safety and performances.

- LigaPASS 2.0 LP Connector (MEDICREA INTERNATIONAL, K160698, primary)

The LigaPASS 2.0 Medial Open Connector components are technologically similar to the already cleared LigaPASS 2.0 LP Connector in terms of intended use and material used. It is similar to the already cleared PASS LP Open Connector in terms of mechanical safety and performances.

- LigaPASS 2.0 LP Connector (MEDICREA INTERNATIONAL, K160698, primary)
- PASS LP Open Connector (MEDICREA INTERNATIONAL, K100297, reference)

7. Non-clinical Test Summary:

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

<u>Biocompatibility Testing</u>
The LigaPASS 2.0 Medial Connector is made from the same materials as its predicates and the manufacturing processes are identical to the ones of the predicates.

<u>Mechanical testing</u>
No additional mechanical testing. Finite element analysis and device descriptive information were sufficient to establish the substantially equivalent mechanical performance of the subject components.

8. Conclusions

The LigaPASS 2.0 Medial and LigaPASS 2.0 Medial Open Connectors components are substantially equivalent to legally marketed predicate devices.