April 3, 2018

Medicrea International S.A.
Mr. David Ryan
Chief Operating Officer
5389 route de Strasbourg – Vancia
Rillieux-la-Pape 69140
FRANCE

Re: K173506
Trade/Device Name: LigaPASS
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: March 5, 2018
Received: March 12, 2018

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.

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.

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,

Ronald P. Jean -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)*
K173506

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, used in sublaminar, or facet wiring techniques
-Spinal reconstruction 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: November 9th 2017

1. **Submitter:**

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

Contact Person:
David RYAN
MEDICREA INTERNATIONAL S.A.
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FR

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, K172021)

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 to introduce the LigaPASS 2.0 Band - B08110005 and the LigaPASS 2.0 Dual Band - B08110010.

MATERIALS: Components in these bands are manufactured from pure titanium that conforms to ASTM F67 and biocompatible 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 Band – B08110005 components are technologically similar to the already cleared LigaPASS 2.0 Band – B08100005 in terms of intended use, material used, mechanical safety and performances.

- LigaPASS 2.0 Band – B08100005 (MEDICREA INTERNATIONAL, K172021)

The LigaPASS 2.0 Dual Band – B08110010 components are technologically similar to the already cleared LigaPASS 2.0 Band – B08100010 in terms of intended use, material used, mechanical safety and performances.

- LigaPASS 2.0 Dual Band – B08100010 (MEDICREA INTERNATIONAL, K172021)

The table below compares the features and characteristics of the submitted LigaPASS 2.0 Bands components to their predicate devices.

Device	***MEDICREA INTERNATIONAL LigaPASS 2.0 Band – B08110005***	***MEDICREA INTERNATIONAL LigaPASS 2.0 Dual Band– B08110010***	**MEDICREA INTERNATIONAL *LigaPASS 2.0 Band***	**MEDICREA INTERNATIONAL *LigaPASS 2.0 Dual Band***
510(k) number	To be determined	To be determined	K172021	K172021
Intended use				
Thoracic	Yes	Yes	Yes	Yes
Lumbar	Yes	Yes	Yes	Yes
Components				
Number of braids	One	Two	One	Two
Braid shape	Flat tubular	Flat tubular	Flat tubular	Flat tubular
Tips	Pure titanium malleable tips	Pure titanium malleable tips	Pure titanium malleable tips	Pure titanium malleable tips
Material				
	PET & Pure titanium (T40) conforming to ASTM F67.	PET & Pure titanium (T40) conforming to ASTM F67.	PET & Pure titanium (T40) conforming to ASTM F67.	PET & Pure titanium (T40) conforming to ASTM F67.

7. Non-clinical Test Summary:

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

Biocompatibility Testing

The LigaPASS 2.0 Band – B08110005 and the LigaPASS 2.0 Dual Band – B08110010 are made from the same materials as its predicates and the manufacturing processes are similar to the ones of the predicates.

Mechanical testing

The tests performed on the LigaPASS 2.0 Dual Band – B08110010 (static traction according to standard NF EN ISO 13934-1) indicate that the product is mechanically equivalent to its predicates.

8. Conclusions

The LigaPASS 2.0 Band – B08110005 and the LigaPASS 2.0 Dual Band – B08110010 are substantially equivalent to legally marketed predicate devices.