May 24, 2022

Medicrea International S.A.
℅ Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC.
803 7th Street NW
Washington, District of Columbia 20001

Re: K213659
Trade/Device Name: LigaPASS™ 2.0 Ligament Augmentation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: April 22, 2022
Received: April 22, 2022

Dear Justin Eggleton:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213659

Device Name
LigaPASS™ 2.0 Ligament Augmentation System

Indications for Use *(Describe)*
The LigaPASS™ system is an implant for use in orthopaedic 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 are as follows:

- 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, adults scoliosis and kyphosis;
- Spine degenerative surgery as an adjunct to spinal fusions.
- Intended for use with a posterior spinal instrumentation construct when ligament augmentation is needed.

The LigaPASS™ system may also be used in conjunction with other medical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	LigaPASS™ 2.0 Ligament Augmentation System
Manufacturer:	Medicrea International S.A. 5389 Route De Strasbourg-Vancia Rillieux-La-Pape 69140, France
Contact:	Justin Eggleton Vice President, Spine Regulatory Affairs (202) 552-5804 jeggleton@mcra.com
Prepared by:	MCRA, LLC 803 7th Street NW Washington, DC 20001 Office: 202.552.5800
Date Prepared:	May 18, 2022
Classification:	Bone fixation cerclage
Class:	II
Product Code:	OWI (21 CFR §888.3010)
Primary Predicate:	LigaPASS™ 2.0 Band and Dual Band (K173506)
Additional Predicate:	LigaPASS™ 2.0 Medial and Medial Open Connector (K172021), Pass LP (K112736)

Indications For Use:

The LigaPASS™ system is an implant for use in orthopaedic 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 are as follows:

- 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, adults scoliosis and kyphosis;
- Spine degenerative surgery as an adjunct to spinal fusions.
- Intended for use with a posterior spinal instrumentation construct when ligament augmentation is needed.

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

Device Description:
The purpose of this submission is to expand the indications of the LigaPASS™ system to include the use with a posterior spinal instrumentation construct when ligament augmentation is needed.

The LigaPASS™ 2.0 Ligament Augmentation System provides surgeons the ability to mimic anatomical muscle and ligament functionality and stabilization between vertebrae that are collapsed during surgery before fusion. The LigaPASS™ 2.0 Ligament Augmentation System is designed to restore balance and stability as a complement to a posterior thoracolumbar fixation system. Ergonomic instrumentation provides smooth assembly with self-stabilizing tensioners and torque-limiting locking tools. The LigaPASS™ 2.0 Ligament Augmentation System consists of a polyester (PET) band and titanium alloy medial open connector with 2 set screws.

LigaPASS™ bands allow the surgeon to create a posterior vertebra anchorage without the use of a pedicle screw or hook. Instead of a pedicle screw or hook, the LigaPASS™ bands are laced around the vertebra independently of the vertebra anatomy and then connected to a LigaPASS™ connector to make the rod-bone connection.

The LigaPASS™ 2.0 bands are comprised of a PET braid and pure titanium (T40) malleable leads at the ends of the bands. The malleable tips help the surgeon to lace the band around the vertebra. They can be bent by the surgeon to make it pass under and through the vertebral body easier.

The LigaPASS™ connectors allow surgeons to attach a rod to a vertebral body without the use of the pedicle. Instead of a pedicle screw, the LigaPASS™ connector use a facet band to make the rod-bone connection. The connectors are comprised of a connector body, a rod set screw, a locking set screw for the band and a polyester band. The body of these connectors is manufactured from titanium alloy (Ti-6Al-4V). The part is compatible with any rods made of titanium or cobalt chromium alloys between diameters 5.5 mm and 6.0 mm.

Predicate Device:
Medicrea submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the LigaPASS™ 2.0 Ligament Augmentation System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: LigaPASS™ 2.0 Band and Dual Band (K173506)

Additional Predicate: LigaPASS™ 2.0 Medial and Medial Open Connector (K172021), Pass LP (K112736)

Performance Testing Summary:
No additional bench or animal testing was completed for the purpose of this 510(k) submission. The non-clinical performance of the LigaPASS™ 2.0 Medial System has been validated through a series of 510(k) submissions (K172021, K173506).

Clinical data published in the literature were provided to support the use of ligament augmentation with the LigaPASS™ system in adult spinal deformity surgery.[1]

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicates cited above with respect to indications, design, materials, function, manufacturing, and performance.

Device	Medicrea International LigaPASS™ 2.0 Ligament Augmentation System	Medicrea International LigaPASS™ 2.0 Medial/Medial Open Connector	Medicrea International LigaPASS™ 2.0 Band/Dual Band
510(k) Number	K213659 (Subject)	K172021	K173506
Intended Use			
Thoracic	Yes	Yes	Yes
Lumber	Yes	Yes	Yes
Materials	- Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3 - Polyethylene Terephthalate (PET)	- Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3 - Polyethylene Terephthalate (PET)	- Polyethylene Terephthalate (PET)

[1] Safaee, M.M., et al., *Ligament augmentation for prevention of proximal junctional kyphosis and proximal junctional failure in adult spinal deformity.* J Neurosurg Spine, 2018. **28**(5): p. 512-519.

Conclusion:

The subject device and the predicate devices have the same intended use, technological characteristics, materials, and performance. Therefore, the subject device is substantially equivalent to the cited predicate devices.