May 27, 2026

Medicrea International S.A.S
Gautier Liegeon
Senior Regulatory Affairs Specialist
5389 Rte. De Strasbourg
Rillieux-La-Pape, 69140
France

Re: K261374
Trade/Device Name: LigaPASS™ System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: April 27, 2026
Received: April 27, 2026

Dear Gautier Liegeon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHANIE SMITH -S

For 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261374

Please provide the device trade name(s).

LigaPASS™ System

Please provide your Indications for Use below.

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, adult scoliosis and kyphosis,
- Spinal 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 grade implants made of titanium or cobalt-chrome alloy whenever “wiring” may help secure the attachment of other implants.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #:

510(k) Summary

Prepared on: 2026-04-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medicrea International S.A.S
Applicant Address	5389 Rte de Strasbourg Rillieux-la-Pape 69140 France
Applicant Contact Telephone	+33426691903
Applicant Contact	Mr. Gautier LIEGEON
Applicant Contact Email	gautier.liegeon@medtronic.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LigaPASS™ System
Common Name	Bone fixation cerclage
Classification Name	Bone Fixation Cerclage, Sublaminar
Regulation Number	888.3010
Product Code(s)	OWI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211057	LigaPASS Spinal System, CD Horizon Spinal System	OWI
K173506	LigaPASS Spinal System	OWI

Device Description Summary

21 CFR 807.92(a)(4)

The LigaPASS™ MEDICREA™ INTERNATIONAL S.A.S. spinal system is composed of four components, a connector, two set screws and a band. The LigaPASS™ system is designed to stabilize a vertebra in the same manner as a hook around the vertebra during development of solid bony fusion. The LigaPASS™ system must be implanted via a posterior approach to complete a thoraco-lumbar fixation system as the PASS LP™ MEDICREA™ INTERNATIONAL S.A.S. spinal system, UNiD™ Patient Specific Rods or CD HORIZON™ Spinal System.
The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136, with the exception of the band which is manufactured in polyethylene terephtalate (PET) and titanium T40 conforming to ISO 5832-2 specifications and ASTM F67.
As any orthopaedic implant, these implants must not be reused.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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, adult scoliosis and kyphosis,
- Spinal 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 grade implants made of titanium or cobalt-chrome alloy whenever "wiring" may help secure the attachment of other implants.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the same indications for use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices have similar fundamental scientific technology, overall design, dimensions, operative principle intended use, indications and sterilization as the primary predicate device.
The subject device and predicate devices differ in that the subject device is compatible with rod diameters as low as 4.75 mm. Otherwise, the subject device is substantially equivalent to the additional predicates presented in terms of manufacturing mechanism and material.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

To demonstrate the mechanical performance of compatible constructs, Medicrea has performed mechanical tests on the subject device: Axial and torsional grip tests per ASTM F1798. The results from non-clinical tests demonstrates substantial equivalence to the predicate devices.