DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 15, 2015

Medicrea International S.A.
Mr. David Ryan
Marketing & Product Development Director
14 Porte Du Grand Lyon
01700 Neyron
France

Re: K141187
Trade/Device Name: IMPIX ALIF S/A
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: December 17, 2014
Received: December 19, 2014

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 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 yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141187

Device Name
IMPIX ALIF S/A

Indications for Use *(Describe)*
The stand-alone intersomatic IMPIX ALIF S/A implants are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
This device is to be used with autogenous bone graft.
Patients should have a satisfactory course of conservative treatment (usually at least six (6) months of non-operative treatment) prior to treatment with an IMPIX-ALIF-S/A stand-alone cage.

The IMPIX ALIF S/A devices should be used with the three (3) bone screws (Small Footprint) or four (4) bone screws (Medium, Large Footprints) accompanying the device. Otherwise, an additional fixation system (e.g., pedicle screw system) should be implanted.

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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1. DEVICE SUBMITTER

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Contact Person:
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VP Product Development and Marketing
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Date Prepared: 12/01/2015

2. DEVICE

Name of Device: IMPIX ALIF S/A

Common or Usual Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar
Intervertebral Fusion Device With Bone Graft, Lumbar

Classification Name: Intervertebral Body Fusion Device

Regulatory Class: 21 CFR 888.3080- Intervertebral Body Fusion Device

Product Code: OVD; MAX

3. PREDICATE DEVICE

The primary predicate used in this 510(k) notice is:

- The STALIF MIDLINE (Centinel Spine, K101301)

The additional predicates are:

- The IMPIX ALIF Lumbar IBF (MEDICREA TECHNOLOGIE, K083798)
- The IMPIX L (MEDICREA TECHNOLOGIE, K072226)
- The SYNFIX LR (Synthes Spine, K062083)
- The STALIF TT (Surgigraft Limited,K073109)

These predicates have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The MEDICREA® IMPIX ALIF S/A is an intervertebral fusion device with integrated fixation use as an adjunct to fusion. The implant is composed of:

- one PEEK cage with tantalum markers
- either 3 or 4 IMPIX ALIF S/A screws , depending on the footprint of cage considered.

The IMPIX ALIF S/A screw is manufactured from titanium alloy (Ti-6Al-4V) meeting ASTM F136 and ISO 5832-3 standards, and the PEEK cage is manufactured from PEEK OPTIMA® LT1 meeting the ASTM F 2026.The tantalum markers are manufactured from tantalum meeting the ASTMF560 and ISO 13782 standards.

Materials: Titanium alloy (Ti-6Al-4V) and PEEK OPTIMA® LT1 and tantalum

5. INDICATIONS FOR USE

The stand-alone intersomatic IMPIX ALIF S/A implants are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

This device is to be used with autogenous bone graft.

Patients should have a satisfactory course of conservative treatment (usually at least six (6) months of non-operative treatment) prior to treatment with an IMPIX-ALIF-S/A stand-alone cage.

The IMPIX ALIF S/A devices should be used with the three (3) bone screws (Small Footprint) or four (4) bone screws (Medium, Large Footprints) accompanying the device. Otherwise, an additional fixation system (e.g., pedicle screw system) should be implanted.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the features and characteristics of the IMPIX ALIF SA to its predicate device.

Device	IMPIX ALIF SA – New	IMPIX ALIF Lumbar IBF	IMPIX L	STALIF MIDLINE	STALIF TT	SYNFIX LR
510(k) number		K083798	K072226	K101301	K073109	K062083
Lumbar	Yes	Yes	Yes	Yes	Yes	Yes
Anterior Approach	Yes	Yes	No	Yes	Yes	Yes
Design						
Anchorage mean	3 or 4 screws	No	No	3 screws	3 screws	4 screws
Security features	Screws head clipped within the cage	No	No	Titanium ring on the screws clipped in the cage	No	Screw head threaded in a titanium plate
Shape	Anatomical shape	Anatomical shape	Rectangular shape	Semi-cylindrical shape	Semi-cylindrical shape	Rectangular shape
Standalone device	Yes	No	No	Yes	Yes	Yes
Materials						
Ti-6Al 4V	Yes	No	No	Yes	Yes	No
Titanium alloy (TAN)	No	No	No	No	No	Yes
Tatalum	Yes	Yes	Yes	Yes	Yes	Yes
PEEK OPTIMA® LT1	Yes	Yes	Yes	Yes	Yes	Yes

Material composition is identical to other MEDICREA® INTERNATIONAL products that have been cleared via the 510(k) process.

7. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the IMPIX ALIF S/A system was conducted in accordance with the FDA blue book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- ✓ Cytotoxicity
- ✓ Sensitization
- ✓ Irritation
- ✓ Systemic toxicity
- ✓ Pyrogen Testing

According to the standard **ISO 10993-1**, the IMPIX ALIF S/A System is defined as implantable device in contact with tissue and bone and as a permanent contact with the patient.

For chemical composition, the material conform to Ti-6Al-4V ELI, following ASTM F136 and ISO 5832-3 standards, PEEK OPTIMA LT1 following ASTM F2026 standard and Tantalum following ASTM F560 and ISO 13782 standards.

Mechanical testing

Testing in compliance with the FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device was performed for the IMPIX ALIF S/A system and demonstrated substantially equivalent performance to the identified predicate device systems.

The following Mechanical tests were performed:

- FEA testing to determine worst case
- Static and dynamic axial compression (per ASTM F2077-11)
- Static and dynamic compression shear (per ASTM F2077-11)
- Subsidence (per ASTM F2267-04)
- Expulsion (per ASTM Draft Standard F-04.25.02.02)
- Screw clip-out evaluation

Clinical study

No clinical studies were performed.

Animal study

No animal studies were performed.

8. CONCLUSION

MEDICREA® INTERNATIONAL S.A. IMPIX ALIF S/A Spinal System – additional components are substantially equivalent to the already cleared STALIF MIDLINE(Centinel Spine, K101301); STALIF TT (Surgigraft Limited,K073109); SYNFIX LR (Synthes Spine, K062083); IMPIX ALIF Lumbar IBF (MEDICREA TECHNOLOGIE, K083798); IMPIX L (MEDICREA TECHNOLOGIE, K072226) in terms of intended use, materials used, sterilization, mechanical safety and performances