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

November 13, 2017

Medicrea International S.A.
Mr. David Ryan
VP Product Development and Marketing
5389 route de Strasbourg
69140 Rillieux-la-Pape
FRANCE

Re: K163595
Trade/Device Name: IMPIX 3D Print Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 10, 2017
Received: October 13, 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 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 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)*
K163595

Device Name
IMPIX 3D Print cages

Indications for Use *(Describe)*
IMPIX 3D Print cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels 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.

IMPIX 3D Print cages are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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 IMPIX 3D PRINT CAGES

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Posterior Lumbar 3D Print spinal system:

Date Prepared: 09 November 2017

1. Submitter:

MEDICREA INTERNATIONAL
5389 route de Strasbourg – Vancia
69140 Rillieux-La-Pape
FR

Contact Person:

David RYAN
MEDICREA INTERNATIONAL
5389 route de Strasbourg – Vancia
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FR

2. Trade name: IMPIX 3D Print Cages

Regulatory Identification/ Classification

Intervertebral Body Fusion Device with Bone Graft, lumbar
Regulation Number: 21CFR 888.3080
Product Code: MAX
Class II

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

Primary predicate:

- K2M Cascadia Interbody System (K150481)

Additional predicate:

- MEDICREA INTERNATIONAL IMPIX-L (K072226)
- CAPSTONE® Spinal System (K121760)
- MEDICREA IMPIX ALIF (K083798)
- NUVASIVE INTERFIXED SYSTEM (K151214)

No reference devices were used in this submission

4. Description of the device:

The IMPIX 3D Print PLIF, IMPIX 3D Print TLIF, and IMPIX 3D Print TLIF-S are intervertebral lumbar devices, which consists of a variety of shapes and sizes. The implants are manufactured in titanium alloy (Ti-6Al-4V ELI conforming to ASTM F3001 specifications) from additive manufacturing process.

MATERIALS: Titanium Alloy (Ti-6Al-4V) according to the ASTM F3001.

Function: The 3D printed Lumbar cage was developed as an implant:
- To provide immobilization and stabilization of anterior spinal segments
- to augment the development of a solid spinal fusion
- to provide stability to ease fusion
- to be mechanically resistant to allow the fusion of the operated level

5. Indication for Use

IMPIX 3D Print cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels 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.

IMPIX 3D Print cages are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. Substantial equivalence claimed to predicate devices

The IMPIX 3D Print cages are technologically similar to the already cleared Lumbar Interbody Device in terms of intended use, materials used, mechanical safety and performances

- K2M Cascadia Interbody System (K150481)
- MEDICREA INTERNATIONAL IMPIX-L (K072226)
- MEDICREA INTERNATIONAL IMPIX-L (K072226)
- CAPSTONE® Spinal System (K121760)
- MEDICREA IMPIX ALIF (K083798)
- NUVASIVE INTERFIXED SYSTEM (K151214)

7. Non-clinical Test Summary:

Testing was performed on the system following the protocols outlined in ASTM F2077 "*Standard Test Methods for Intervertebral Body Fusion Devices"* and in the ASTM F2267 "*Standard Test Methods Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression".*
The following tests were conducted: Static Compression, Static Compression-shear, Dynamic Compression, Dynamic Compression-shear, Subsidence test, and Expulsion test

8. Clinical Test Summary 0

No clinical studies were performed.
Published literature was used to demonstrate substantial equivalence.

9. Conclusions Non clinical and Clinical

MEDICREA® INTERNATIONAL IMPIX 3D Print Cages are substantially equivalent to its predicate devices in terms of indications for use, design, material and function.