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

April 25, 2018

Re: K173782
Trade/Device Name: UNiD Patient Specific 3D printed cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 26, 2018
Received: March 29, 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,

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)*
K173782

Device Name
UNiD Patient Specific 3D printed cage

Indications for Use *(Describe)*
UNiD 3D printed interbody system device is 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.

UNiD 3D printed interbody system device is 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 UNiD Patient Specific 3D printed cage

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the UNiD 3D printed interbody system.

1. Submitter:

MEDICREA® INTERNATIONAL S.A.

5389 route de Strasbourg - Vancia

69140 RILLIEUX-LA-PAPE- France

Phone: +33 4 72 01 87 87

Fax: +33 4 72 01 87 88

Contact Person:

David RYAN

Chief Operating Officer

dryan@medicrea.com

Date Prepared: 23 Apr 2018

2. Trade name: UNiD Patient Specific 3D printed cage

Common Name: UNiD 3D cage

Classification Name:
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:

- **MEDICREA INTERNATIONAL, IMPIX 3D printed cage (K163595)**

4. Description of the device

The UNiD 3D printed cage is an intervertebral lumbar device, which consists of various implant sizes to adapt the implant to the patient anatomy. 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 ASTM F3001.

Function: The 3D printed Lumbar cage was designed to provide immobilization and stabilization of spinal segments. This stability is intended to facilitate fusion at the treated level(s).

Major dimensions which can be adapted:
- Anterior and posterior heights
- Lordosis
- Length
- Width

5. Indication for Use

UNiD 3D printed interbody system device is 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.
UNiD 3D printed interbody system device is 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 Lumbar Interbody Device are technologically similar to the already cleared Lumbar Interbody Device in terms of intended use, materials used, mechanical safety and performances

- MEDICREA INTERNATIONAL IMPIX 3D printed interbody system (K163595)

The table below compares the features and characteristics of 3D printed Lumbar cages to their predicate devices.

Device	UNiD 3D cage	IMPIX 3D PLIF
510(k) number	K173782	K163595
Intended use		
Lumbar spine (L2-S1)	Yes	Yes
Approach	Posterior	Posterior
Design		
Shape	Rectangular anatomical shape	Rectangular anatomical shape
Dimensions	Lengths: 15 to 40 mm Heights: 6 to 20 mm Width: 8 to 12 mm Lordosis angles: 0° to 22°	Lengths : 15 to 40 mm Heights : 6 to 20 mm Width: 8 to 12 mm Lordosis angles : 0° to 22°
Cage	Titanium Alloy (Ti-6Al-4V) according to the ASTM F3001	Titanium Alloy (Ti-6Al-4V) according to the ASTM F3001
	Provided Sterile (Gamma sterilized) or non-sterile (steam sterilization) - Single use only	Provided Sterile (Gamma sterilized) - Single use only

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 and Subsidence test

8. Clinical Test Summary

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical

MEDICREA® INTERNATIONAL UNiD 3D printed Lumbar Interbody Device are substantially equivalent to its predicate device in terms of indications for use, design, materials and function.