Medicrea International S.A.
Mr. David Ryan
Chief Operation Officer
5389 route de Strasbourg – Vancia
Rillieux-la-Pape 69140
France

July 15, 2019

Re: K182158
Trade/Device Name: UNiD Patient-matched PLIF cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 11, 2019
Received: June 13, 2019

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. 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,

for Melissa Hall
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182158

Device Name
UNiD Patient-matched PLIF cage

Indications for Use *(Describe)*
UNiD Patient-matched PLIF cage is indicated for lumbar spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels form 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 bone graft.

UNiD Patient-matched PLIF cage 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
MEDICREA INTERNATIONAL's UNiD Patient-matched PLIF cage

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the UNiD Patient-matched PLIF cage:

Date Prepared: July, 30, 2018

1. **Submitter:**

MEDICREA INTERNATIONAL
5389 route de Strasbourg – Vancia
RILLIEUX-LA-PAPE 69140
FR

Contact Person:
David RYAN
MEDICREA INTERNATIONAL
5389 route de Strasbourg - Vancia
RILLIEUX-LA-PAPE 69140
FR

2. **Trade name:** UNiD Patient-matched PLIF cage

Common name : UNiD patient-matched PLIF cage

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

Additional predicate:
- MEDICREA INTERNATIONAL, UNiD Patient Specific 3D Printed cage (K173782)

4. **Description of the device:**

The UNiD patient-matched PLIF cage is an intervertebral lumbar device, designed to match the anatomy of an individual patient from patient imaging data (X-Ray, MRI, CT). The implant is 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 UNiD patient-matched PLIF cage is developed as an implant:

- To provide immobilization and stabilization of posterior spinal segments
- to increase 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

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

5. Indication for Use

The UNiD patient-matched PLIF cage is designed individually for each patient and 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.
The UNiD patient-matched PLIF cage 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 UNiD patient-matched PLIF cage devices are technologically similar to the already cleared MEDICREA INTERNATIONAL, IMPIX 3D printed cage (K163595) and MEDICREA INTERNATIONAL, UNiD Patient Specific 3D Printed cage (K173782) in terms of intended use, material used, mechanical safety and performances.

The table below compares the features and characteristics of the submitted UNiD patient-matched PLIF cage devices to their predicate devices.

Device	***MEDICREA INTERNATIONAL Submit UNiD patient-matched PLIFPLIF cage***	**MEDICREA INTERNATIONAL *IMPIX 3D PLIF***	**MEDICREA INTERNATIONAL *UNiD Patient Specific 3D Printed cage***
510(k) number	K182158	K163595	K173782
Intended use			
Lumbar	Yes	Yes	Yes
Material			
	Titanium Alloy (Ti-6Al-4V) according to the ASTM F3001	Titanium Alloy (Ti-6Al-4V) according to the ASTM F3001	Titanium Alloy (Ti-6Al-4V) according to the ASTM F3001
Caracteristics			
Shape	Rectangular anatomical shape	Rectangular anatomical shape Flat endplates	Rectangular anatomical shape Flat endplates

Device	***MEDICREA INTERNATIONAL Submit UNiD patient-matched PLIFPLIF cage***	**MEDICREA INTERNATIONAL *IMPIX 3D PLIF***	**MEDICREA INTERNATIONAL *UNiD Patient Specific 3D Printed cage***
	Patient-matched endplates		
Dimensions	Lengths: 15 to 40 mm Heights: 6 to 20 mm Width: 8 to 12 mm Lordosis angles: 0° to 22° Height strut ≤2,85mm Width strut ≤2,5mm	Lengths: 15 to 40 mm Heights: 6 to 20 mm Width: 8 to 12 mm Lordosis angles: 0° to 22° Height strut ≤2,85mm Width strut ≤2,5mm	Lengths: 15 to 40 mm Heights: 6 to 20 mm Width: 8 to 12 mm Lordosis angles: 0° to 22° Height strut ≤2,85mm Width strut ≤2,5mm
Sterilization	Provided Sterile (Gamma sterilized) or non-sterile (steam sterilization) - Single use only	Provided Sterile (Gamma sterilized) - Single use only	Provided Sterile (Gamma sterilized) or non-sterile (steam sterilization) - 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 patient-matched PLIF cage is substantially equivalent to its predicate device in terms of indications for use, design, materials and function.