October 30, 2020

Medicrea International S.A.
David Ryan
Chief Operating Officer
5389, route de Strasbourg
Rillieux-la-Pape, 69140
France

Re: K200316
Trade/Device Name: UNiD® IB3D ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 30, 2020
Received: October 2, 2020

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,

Brent Showalter, Ph.D.
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)*
K200316

Device Name
UNiD® IB3D ALIF

Indications for Use *(Describe)*
MEDICREA® INTERNATIONAL UNiD® IB3D ALIF device is designed individually for each patient and indicated for spinal 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® IB3D ALIF 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.

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

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510(k) SUMMARY
MEDICREA® INTERNATIONAL's UNiD® IB3D ALIF

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the UNiD® IB3D ALIF:

Date Prepared: February 3, 2020

1. Submitter:

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5389 route de Strasbourg – Vancia
RILLIEUX-LA-PAPE 69140
FR
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Contact Person:

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

2. Trade name: UNiD® IB3D ALIF

Regulatory Identification/ Classification

FDA 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 device:

- IB3D ALIF, (MEDICREA® INTERNATIONAL, K191134)

Reference Devices:

- UNiD® Patient matched PLIF cage, (MEDICREA® INTERNATIONAL, K182158)
- UNiD® Patient Specific 3D printed cage (MEDICREA® INTERNATIONAL, K173782)
- IMPIX® 3D printed cages (MEDICREA® INTERNATIONAL, K163595)

Those three devices have not been subject to a design-related recall.

4. Description of the device:

The MEDICREA® INTERNATIONAL UNiD® IB3D ALIF device consists of one single implant with specific heights, footprint, lordosis and coronal angle. Patient matched endplates can be added to the implant. It is intended for insertion between two adjacent vertebrae by an anterior approach. The MEDICREA® INTERNATIONAL implant is manufactured from titanium alloy Ti-6Al-4V ELI following ASTM F3001 standard, a radio opaque material. As any orthopaedic implant, these implants should not be reused. For a complete guide of the system, please refer to the surgical technique manual for specific instructions.
The UNiD® IB3D ALIF cage is designed for a specific patient, it must not be used for another patient.

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

Function:

The UNiD® IB3D ALIF was developed as an implant:

- to provide immobilization and stabilization of posterior 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

MEDICREA® INTERNATIONAL UNiD® IB3D ALIF device is designed individually for each patient and indicated for spinal 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® IB3D ALIF 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 UNiD® IB3D ALIF are technologically similar to the already cleared MEDICREA® INTERNATIONAL IB3D ALIF in terms of intended use, material used, mechanical safety and performances.

The table below compares the features and characteristics of the submitted UNiD® IB3D ALIF to its predicate device.

Device	***MEDICREA® INTERNATIONAL UNiD® IB3D ALIF***	***MEDICREA® INTERNATIONAL IB3D ALIF***
510(k) number	K200316	K191134
Intended use		
Lumbar	Yes	Yes
Approach	Anterior	Anterior
Material		
Raw material	Titanium Ti6Al4V ELI	Titanium Ti6Al4V ELI
Sterilization		
Sterilization	Provided sterile or non-sterile	Provided sterile

7. Non-clinical Test Summary:

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

Biocompatibility Testing
The UNiD® IB3D ALIF are made from the same materials as its predicates and the manufacturing processes are similar to the ones of the predicates.

Mechanical testing

Finite Element Analysis (FEA) was conducted and it was determined that no new worst-case implant was created. Therefore additional testing per ASTM F2077 "*Standard Test Methods for Intervertebral Body Fusion Devices"* and ASTM F2267 "*Standard Test Methods Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression"* was not conducted.

8. Conclusions

UNiD® IB3D ALIF devices are substantially equivalent to legally marketed predicate device