October 29, 2021

Medacta International S.A.
% Mr. Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K212831
Trade/Device Name: MectaLIF Extension
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 3, 2021
Received: September 7, 2021

Dear Mr. Lussier:

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 L. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212831

Device Name
MectaLIF Extension

Indications for Use *(Describe)*

The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

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

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: October 22, 2021

II. Device

Device Proprietary Name:	MectaLIF Extension
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Primary Product Code:	MAX
Regulation Number:	21 CFR 888.3080
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- MectaLIF TiPEEK, K133192, Medacta International SA

In addition, the following additional predicate devices are cited within the submission:

- Aleutian IBF System, K130699, K2M, Inc.
- MectaLIF, K110927, Medacta International SA
- MectaLIF Extension, K131671, Medacta International SA
- MectaLIF Posterior Extension, K181970, Medacta International SA

IV. Device Description

The subject MectaLIF Extension implants are a line extension to the MectaLIF Oblique and Posterior PEEK implants (K110927, K131671 and K181970) and MectaLIF Oblique and Posterior TiPEEK implants (K133192 and K181970).

MectaLIF implants are used to replace a degenerative disc in order to restore the height of the spinal column structure. The devices are not intended to be coupled with other implants but are intended to be used with supplemental fixation and autogenous bone graft.

The subject MectaLIF Extension includes the following implants:

- MectaLIF Oblique with width 12mm, ***new length 24mm***, height from 7 to 15mm, lordosis 0°, 5° and 10°
- MectaLIF Oblique with ***new width 10***, length from 24 to 36, height from 7 to 15, lordosis 0°, 5° and 10°
- MectaLIF Posterior with width 9mm and 11mm, ***new length 19mm***, height from 7 to 15mm, lordosis 0°, 5°, 10°, 15° and 20°
- MectaLIF Posterior with width 9mm and 11mm, length 19mm, 22mm and 25mm, height from 9 to 15mm, ***new lordosis 12°***
- MectaLIF Posterior with width 9mm, length 19mm, 22 and 25mm, height from 13 to 15mm, ***new lordosis 15° and 20°***

The MectaLIF Extension implants are made of implant grade Polyetherketone according to ASTM F2026-17 and they have marker made of Tantalum according to ISO 13782:2019 and ASTM F560-17.

The subject devices are available both uncoated or coated with commercially pure titanium coating according to ASTM F1580-18.

V. Indications for Use

The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

VI. Comparison of Technological Characteristics

The MectaLIF Extension implants and the predicate devices share the following characteristics:

- design;
- materials;
- coating;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The MectaLIF Extension implants differ from the predicate devices with respect to:

- range of product sizes;
- lordosis; and
- bone graft volume.

VII. Performance Data

Based on the risk analysis, design validation and performance testing were conducted to written protocols. The following validation and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *DESIGN VALIDATION*
  - MectaLIF Oblique 10mm width instrument/implant interface, Design Validation Report

- *PERFORMANCE TESTING*
  - Mechanical standard tests on MectaLIF Oblique and MectaLIF Posterior lumbar cages for interbody fusion according to ASTM F2077-18 *Test Methods For Intervertebral Body Fusion Devices* and ASTM F2267-04 (reapproved 2018) *Standard Test Method for Measuring Load Induced subsidence of Intervertebral Body Fusion Device under Static Axial Compression* including:
    - static and dynamic axial compression test
    - static and dynamic shear compression test
    - axial compressive subsidence test
  - TiPEEK coating validation according to ASTM F1854-15 *Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants* and ASTM F1147-05 (reapproved 2017)e1 *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings*
  - Wear analysis of TiPEEK coated intervertebral body fusion devices according to ISO 17853:2011 *Wear of implant materials - Polymer and metal wear particles - Isolation and characterization* and ASTM F1877-16 *Standard Practice for Characterization of Particles*
  - Expulsion Test rationale

- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic

- *BIOCOMPATIBILITY ASSESSMENT*

- *SHELF-LIFE EVALUATION*

Clinical Studies:

- No clinical studies were conducted

VIII. Conclusion

The information provided above supports that the MectaLIF Extension implants are substantially equivalent to the predicate devices.