October 24, 2022

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

Re: K221545
Trade/Device Name: MectaLIF Anterior Extension
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: September 23, 2022
Received: September 26, 2022

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 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)*
K221545

Device Name
MectaLIF Anterior Extension

Indications for Use *(Describe)*
The MectaLIF Anterior is an interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The interior of the spacer component of the MectaLIF Anterior can be packed with autograft or autologous bone graft. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The MectaLIF Anterior Stand-Alone system is intended to be used with bone screws provided and requires no additional supplementary fixation. The MectaLIF Anterior Simple requires additional supplementary fixation such as pedicle screws and rods or lumbar anterior plate system.

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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K221545
510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: May 25, 2022
Date Revised: June 28, 2022

II. Device

Device Proprietary Name:	MectaLIF Anterior Extension
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with with Integrated Fixation, Lumbar
Primary Product Code:	OVD
Regulation Number:	21 CFR 888.3080
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary predicate device:

- MectaLIF Anterior, K124034, Medacta International SA

Additional predicate devices:

- MectaLIF Anterior Stand Alone, K160605, Medacta International SA
- MectaLIF Anterior Stand Alone, K170455, Medacta International SA
- Lanx Fusion System, K102738, Lanx Inc.

IV. Device Description

The subject MectaLIF Anterior Extension implants are a line extension designed to provide a larger product offering in Medacta MectaLIF Anterior portfolio.

The MectaLIF Anterior is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. The family of MectaLIF Anterior system features two designs:

- MectaLIF Anterior Stand-Alone Fusion Device System, which is a system consisting of cages, plates and is intended to be used with bone screws provided and requires no additional supplementary fixation.
- MectaLIF Anterior Simple, which is a cage/plate system requiring additional supplementary fixation.

The purpose of this submission is to introduce new cages footprints as well as new plates and screws designs.

Identically to already cleared MectaLIF Anterior implants, the subject MectaLIF Anterior Extension implants consists of disc spacers made of PEEK Implant Grade Polyetheretherketone (ASTM F2026) body coated with commercially pure titanium (CPTi, ASTM F1580). The spacers contain tantalum markers (ISO 13782 / ASTM F560) and include a flush plate secured to the vertebral body with 4 bone screws. Both the plates and the screws are made of Ti6Al4V ELI (ISO 5832-3/ASTM F136). The flush plate is secured to the disc spacer via an interlocking mechanism and it is available in two designs lock and lag where an additional anti-back-out cover plate is used to reduce the risk of screw migration after the implantation. The interior of the disc spacer can be packed with autograft or autologous bone graft.

V. Indications for Use

The MectaLIF Anterior is an interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The interior of the spacer component of the MectaLIF Anterior can be packed with autograft or autologous bone graft. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The MectaLIF Anterior Stand-Alone system is intended to be used with bone screws provided and requires no additional supplementary fixation. The MectaLIF Anterior Simple requires additional supplementary fixation such as pedicle screws and rods or lumbar anterior plate system.

VI. Comparison of Technological Characteristics

The MectaLIF Anterior Extension implants and the Medacta predicate devices (K124034, K160605 and K170455) are substantially equivalent with regards to the following characteristics:

- lordosis;
- screw sizes and tip;
- materials;
- coating;
- biocompatibility;
- device usage;

- sterility;
- shelf life; and
- packaging.

The MectaLIF Anterior Extension implants differ from the Medacta predicate devices (K124034, K160605 and K170455) with respect to:

- cages footprints;
- bone graft volume; and
- lag design, including lag plates, lag screws and cover plate.

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 Anterior Design Validation Report

- *PERFORMANCE TESTING*

  - Mechanical standard tests on MectaLIF Anterior interbody fusion devices 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
    - static and dynamic shear compression test without pockets
    - static and dynamic torsion test
    - axial compressive subsidence test
    - static expulsion test
  - MectaLIF Anterior lag screws static tests according to ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws* including:
    - static torsion strength test, including breaking angle
    - insertion and removal torque test
    - pull-out strength test
  - 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*

- *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 or pyrogen free.

- *BIOCOMPATIBILITY* assessment

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

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