October 18, 2023

Medacta International S.A.
℅ Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K232123
Trade/Device Name: MectaLIF Anterior Lag Extension
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 17, 2023
Received: August 3, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
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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.

Submission Number *(if known)*

K232123

Device Name

MectaLIF Anterior Lag 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.

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, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: July 17, 2023

II. Device

Device Proprietary Name:	MectaLIF Anterior Lag Extension
Common or Usual Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification Name:	Intervertebral body fusion device
Primary Product Code	OVD
Regulation Number:	21 CFR 888.3080
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- MectaLIF Anterior Extension, K221545, Medacta International SA.

IV. Device Description

MectaLIF Anterior Stand Alone Fusion Device System, consisting of cages, plates and screws, does not require additional fixation. The MectaLIF Anterior cage can be coupled with four different profiles of stand-alone plates: flush, long, L5-S1 and hybrid.
The purpose of this submission is to gain the clearance for a design change performed on the MectaLIF Anterior lag plates flush and their related cover plate already cleared within K221545.
The lag plate flush is secured to the disc spacer via an interlocking mechanism and an additional anti-back-out cover plate, used to reduce the risk of screw migration after the implantation.
No materials' changes have been performed, thus both the plates and the screws are made of Ti6Al4V ELI (ISO 5832-3/ASTM F136).

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 subject MectaLIF Anterior Lag Extension implants are identical to the predicate devices with regards to the following characteristics:

- Indications for use;
- System's device components;
- General design;
- Material;
- Biocompatibility;
- Device usage;
- Sterility;
- Shelf-life; and
- Packaging.

The only differences between the subject and the predicate devices are related to the design changes implemented on the sub-components of lag plates flush and cover plate.

Discussion

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness as demonstrated by the risk analysis provided within the submission.

Medacta International SA has not made any change to the indications for use, manufacturing process, material, device usage, biocompatibility, sterility, shelf life and packaging of the subject devices with respect to the predicate devices.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validations and tests support the substantial equivalence determination:

<u>Non-Clinical Studies</u>

- *PERFORMANCE TESTING*
  - Simulated-use testing to confirm that, during operation according to the surgical technique, the device can achieve its intended use.
  - Simulated-use testing to confirm that, in case of potential misuse generated by fastening attempt with the Cover Plate off axis, the device can achieve its intended use.
  - Resistance testing to confirm that the resistance of the Flush Plate-Cover Plate interface is above the required strength.

- *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 evaluation*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the subject devices are substantially equivalent to the predicate devices.