March 9, 2020

Medacta International SA
% Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K200048
Trade/Device Name: MectaLIF Anterior Simple
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 6, 2020
Received: January 9, 2020

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,

for
Brent L. Showalter, Ph.D.
Assistant Director (Acting)
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)*

K200048

Device Name
MectaLIF Anterior Simple

Indications for Use *(Describe)*

The MectaLIF Anterior is an anterior 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 System 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 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 a system 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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2.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director, Quality and Regulatory, Medacta USA
Date Prepared: January 6, 2020
Date Revised: February 24, 2020

II. Device

Device Proprietary Name:	MectaLIF Anterior Simple
Common or Usual Name:	Anterior 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 device:

- Primary Predicate: MectaLIF Anterior, K124034, Medacta International SA

The following are additional predicate devices**:**

- MectaLIF Anterior Stand Alone, K160605, Medacta International SA
- MectaLIF Anterior Stand Alone, K170455, Medacta International SA

IV. Device Description

The MectaLIF Anterior Simple devices are interbody fusion devices which require supplementary fixation such as pedicle screws and rods or a lumbar anterior plate system. The design incorporates the benefits of a modular anterior plate and a radiolucent interbody spacer; the plate is secured to the disc spacer via an interlocking mechanism.

The plates, manufactured from Ti6Al4V ELI (ISO 5832-3 and ASTM F136), are provided sterile and are offered in five (5) heights (10 – 18 mm).

The spacers, cleared under K124034, K160605, and K170455, are manufactured from PEEK and Ti-PEEK.

V. Indications for Use

The MectaLIF Anterior is an anterior 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 System 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 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 a system 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 Simple and the predicate device share the following characteristics:

- size;
- materials of construction;
- biocompatibility;
- device usage;
- sterilization method;
- shelf life; and
- packaging.

The MectaLIF Anterior Simple and the predicate devices are technologically different as the subject devices are not stand-alone products; therefore, they are not provided with bone screws and supplementary fixation is required.

VII. Performance Data

The MectaLIF Anterior plates were tested per ASTM F2077-11, ASTM F2267-04 (reapproved 2011), ASTM F1877-05 (reapproved 2010), and ISO 17853:2011 using the worst-case device for each of the following tests:

- static axial compression;
- dynamic axial compression;

- static compression-shear;
- dynamic compression-shear;
- static torsion;
- dynamic torsion;
- subsidence; and
- expulsion.

In addition, the Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination.

Worst-case analysis was conducted on the MectaLIF Anterior plate family. It was determined that the MectaLIF Anterior Simple does not introduce new worst-case plate when compared to the previously cleared plates (K124034); therefore, additional verification testing is not required.

VIII. Conclusion

The information provided above supports that the MectaLIF Anterior Simple plates are substantially equivalent to the identified predicate device.