July 17, 2025

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

Re: K251016
Trade/Device Name: MectaLIF 3D Metal
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 2, 2025
Received: June 18, 2025

Dear Christopher 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251016

Please provide the device trade name(s).

MectaLIF 3D Metal

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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 and Regulatory, Medacta USA
Date Prepared: April 02, 2025

II. Device

Device Proprietary Name:	MectaLIF 3D Metal
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 predicate devices.

Primary Predicate device:

- MectaLIF Extension, K212831, Medacta International SA

Additional Predicate devices:

- MectaLIF Posterior Extension, K181970, Medacta International SA
- MectaLIF TiPEEK, K133192, Medacta International SA
- MectaLIF Extension, K131671, Medacta International SA
- MectaLIF, K110927, Medacta International SA

Reference devices:

- Mpact 3D Metal Implants – DMLS Technology, K202568, Medacta International SA
- GMK 3D Metal Tibial Tray, K221850, Medacta International SA

IV. Device Description

The MectaLIF 3D Metal are a line extension to the MectaLIF Oblique and Posterior PEEK implants (K110927, K131671, K181970 and K212831) and MectaLIF Oblique and Posterior TiPEEK implants

(K133192, K181970 and K212831). Specifically, the purpose of this submission is to obtain the clearance of MectaLIF 3D Metal Posterior, Oblique and Oblique Dome additively manufactured from Ti6Al4V according to ASTM F2924-14.
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 implants are provided individually packed, sterile and single-use.

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 subject and predicate devices (K212831, K181970, K133192, K131671 and K110927) are substantially equivalent with respect to the following characteristics:

- Range of product;
- Design;
- Endplate shape, except for the dome;
- Biocompatibility;
- Device usage;
- Packaging; and
- Sterilization.

The subject devices differ from the predicate devices (K212831, K181970, K133192, K131671 and K110927) with respect to:

- Endplate surface;
- Bone graft volume;
- Material; and
- Shelf-life.

Discussion
The dome shape of the subject MectaLIF Oblique 3D Metal does not raise any new issue of safety and effectiveness since it allows to reach the same lordosis of the predicate devices (K212831, K181970, K133192, K131671 and K110927).
The different endplate surface of the subject devices does not affect safety and effectiveness since saw teeth have a height similar to the pyramids of the predicate devices (K212831, K181970, K133192, K131671 and K110927), but they allow a preferential insertion direction while keeping the same resistance to backout.
All the subject devices, except for the smallest size of the subject MectaLIF 3D Metal posterior, have a bone graft volume equal or higher than the smallest predicate device. Also, the ratio between the bone

graft volumes of the smallest subject and predicate device is slightly different (<9%), thus it does not raise any new issue in terms of safety and effectiveness.
The different material has not any impact on the subject devices' safety and effectiveness as both the material and the manufacturing process is shared with the reference devices (K202568, K221850).
The shelf-life of the subject devices is currently 5 years, identically to the one of the predicate devices, but there is an ongoing project to extend this shelf-life to 10 years since validation tests confirming 10 years shelf-life have been already performed according to ISO 11607-1 and ISO 11607-2, thus no new issue of safety and effectiveness arise.

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 tests are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Mechanical standard tests on 3D printed 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* and ISO 23089-2 *Implants for surgery - Preclinical mechanical assessment of spinal implants and particular requirements - Part 2: Spinal intervertebral body fusion devices* including:
    - static and dynamic axial compression test
    - static and dynamic shear compression test
    - axial compressive subsidence test
  - Expulsion test
  - Wear analysis 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*
  - Stereological evaluation according to ASTM F1854 - 15 *Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants*
  - Abrasion test according to ASTM F1978-22 *Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser*
  - Static tensile test according to ASTM F1147-05 *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings*
  - Static shear test according to ASTM F1044-05 *Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings*

- *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 subject devices are substantially equivalent to the predicate devices.