



May 5, 20206

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

Re: K254202
Trade/Device Name: MectaLIF 3D Metal Anterior
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: April 10, 2026
Received: April 10, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

KATHERINE D. KAVLOCK -S

for

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

510(k) Number (if known)
K254202

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Device Name
MectaLIF 3D Metal Anterior

Indications for Use (Describe)

• MectaLIF 3D Metal Anterior

The MectaLIF 3D Metal 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 3D Metal Anterior should 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 3D Metal Anterior Stand-Alone system is intended to be used with bone screws provided and requires no additional supplementary fixation.

MectaLIF 3D Metal Anterior with a lordotic angle greater than 20° will require additional supplemental fixation such as pedicle screws and rods.

• MectaLIF Anterior

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 should 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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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: December 24, 2025
Date Revised: April 30, 2026

II. Device

Device Proprietary Name:	MectaLIF 3D Metal Anterior
Common or Usual Name:	Intervertebral body fusion device
Classification Name:	Intervertebral Fusion Device 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 predicate devices.

Primary Predicate device:

- MectaLIF Anterior Lag Extension, K232123, Medacta International SA

Additional Predicate devices:

- MectaLIF Anterior, K124034, Medacta International SA
- MectaLIF Anterior Stand Alone, K160605, Medacta International SA
- MectaLIF Anterior Stand Alone, K170455, Medacta International SA
- MectaLIF Anterior Extension, K221545, Medacta International SA

Reference devices:

- MectaLIF 3D Metal, K251016, Medacta International SA

IV. Device Description

The MectaLIF 3D Metal Anterior is a line extension designed to provide a larger product offering in Medacta MectaLIF Anterior portfolio indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1.

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. Specifically, the purpose of this submission is to obtain clearance for the following implantable, sterile and single-use devices:

- MectaLIF 3D Metal Anterior additively manufactured from Ti6Al4V according to ASTM F2924-14
- MectaLIF Anterior lag low profile antibackout cover plates made of Ti6Al4V ELI according to ISO 5832-3 and ASTM F136-13.

V. Indications for Use

- MectaLIF 3D Metal Anterior

The MectaLIF 3D Metal 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 3D Metal Anterior should 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 3D Metal Anterior Stand-Alone system is intended to be used with bone screws provided and requires no additional supplementary fixation.

MectaLIF 3D Metal Anterior with a lordotic angle greater than 20° will require additional supplemental fixation such as pedicle screws and rods.

- MectaLIF Anterior

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 should 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 and predicate devices (K232123, K124034, K160605, K170455 and K221545) are substantially equivalent with respect to the following characteristics:

- Design, except for the low profile antibackout cover plates;
- Range of product, except for the low profile antibackout cover plates;
- Low profile antibackout cover plates material;
- Biocompatibility;
- Device usage;
- Packaging; and
- Sterilization.

The subject devices differ from the predicate devices (K232123, K124034, K160605, K170455 and K221545) with respect to:

- Endplate shape;
- Endplate surface;
- MectaLIF 3D Metal Anterior cages material;
- Low profile antibackout cover plates design;
- Low profile antibackout cover plates range of product;
- Low profile antibackout cover plates coupling with the flush plate; and
- Shelf-life.

Discussion

The additional 25° endplate shape of the subject devices has been designed to enlarge the product portfolio providing more options for the surgeons, but it does not affect safety and effectiveness since from a mechanical point of view it does not introduce any new worst case.

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 (K124034, K160605, K170455 and K221545), but they allow a preferential insertion direction while keeping the same resistance to backout. The different material of the subject MectaLIF 3D Metal Anterior cages 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 (K251016).

The different design between the subject low profile antibackout cover plates and the predicate device (K221545 and K232123) does not affect the function since both the shapes prevent the antibackout of the screws.

The different heights of the subject low profile antibackout cover plates with respect to the single size of the predicate device (K221545 and K232123) does not introduce any new risk with respect to safety and effectiveness since they have been designed according to the height of the corresponding MectaLIF Anterior Lag Plate Flush. Also, the height is laser marked and the devices are color coded.

The different approach to reach the proper orientation on the plate of the subject and predicate (K221545 and K232123) cover plates does not affect safety and effectiveness since the same locking mechanism is used.

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 with 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

DESIGN VALIDATION

- MectaLIF Anterior 3D Printed Cages, Design Validation
- ALIF LAG Antibackout Plate Reduced Profile, Design Validation
- ALIF LAG Antibackout Plate comparison

PERFORMANCE TESTING

- Mechanical standard tests on 3D printed MectaLIF 3D Metal Anterior cages for interbody fusion according to ASTM F2077-18, ASTM F2267-04 and ISO 23089 including:
 - Static and Dynamic Axial Compression;
 - Dynamic Axial Compression;
 - Static and Dynamic Shear Compression with and without pocket;
 - Static and Dynamic Torsion;
 - Subsidence; and
 - Expulsion.
- Wear analysis according to ISO 17853
- Gyroid lattice structure characterization testing - Rationale
- MectaLIF Anterior Antibackout Plate LP, Limit test

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.