March 15, 2019

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

Re: K183426
Trade/Device Name: MectaLIF Anterior Stand Alone Extension
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: February 6, 2019
Received: February 7, 2019

Dear Chris 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K183426

Device Name
MectaLIF Anterior Stand Alone Extension

Indications for Use *(Describe)*

The MectaLIF Anterior Stand Alone system 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 Stand Alone 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. The MectaLIF Anterior Stand-Alone system is a system intended to be used with bone screws provided and requires no additional supplementary fixation. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA Date Prepared: December 10, 2018

II. Device

Device Proprietary Name:	MectaLIF Anterior Stand Alone Extension
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 devices:

Primary Predicate:

- MectaLIF Anterior Stand Alone – K160605 – Medacta International S.A

Reference Devices:

- MectaLIF Anterior – K124034 – Medacta International S.A
- MectaLIF Anterior Stand Alone Extension – K170455 – Medacta International S.A

IV. Device Description

The MectaLIF Anterior Stand Alone devices are stand-alone anterior interbody fusion devices indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. MectaLIF Anterior Stand Alone is intended to be used with the provided bone screws and requires no additional supplementary fixation.

MectaLIF Anterior Stand Alone consists of disc spacers made of PEEK Implant Grade Polyetheretherketone. The spacers are provided uncoated or coated with a commercially pure titanium

(CPTi). Both uncoated and coated spacers contain tantalum markers, and include titanium bone screws and a titanium plate.
The interior of the disc spacer can be packed with autograft or autologous bone graft. The plate comes in four different designs (Flush, Long, L5-S1, and Hybrid) and is secured to the disc spacer via an interlocking mechanism. The disc spacer and attached plate are secured to the vertebral body with the bone screws. The Flush, Long, and Hybrid plates are used with four bone screws while the L5-S1 plate is used with three bone screws.

The MectaLIF Anterior cages, plates and bone screws were cleared under K124034, K160605, and K170445.

The subject MectaLIF Anterior Stand Alone Extension introduces Long Head Screw implants that are line extension to the previously cleared Medacta International MectaLIF Anterior Stand Alone – K160605.

The MectaLIF Anterior Long Head Screw implants have been designed with the same or similar shape, dimensions and materials as the previously cleared Medacta MectaLIF Anterior Stand Alone screws (K160605): they share the lengths, the diameters, the material and the body shape, the only difference is the longer screw head (compared to current Medacta MectaLIF Anterior screws already on the market) and the tighter coupling dimensions (Torx interface) developed to allow better stability between the screw and the screwdriver during screw implantation.

The MectaLIF Anterior Long Head Screw implants are manufactured with the same material as the Medacta predicate device MectaLIF Anterior Stand Alone screws [cleared through K160605]: Ti-6Al-4V ELI (*ISO 5832-3 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy + ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*).

V. Indications for Use

The MectaLIF Anterior Stand Alone system 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 Stand Alone 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. The MectaLIF Anterior Stand-Alone system is a system intended to be used with bone screws provided and requires no additional supplementary fixation. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

VI. Comparison of Technological Characteristics

The MectaLIF Anterior Stand Alone Extension implants and the predicate device share the following characteristics:

- Sizes (length and diameter);
- range of products;
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The MectaLIF Anterior Stand Alone Extension is technologically different from the predicate device as follows:

- screw head design (Length and Torx interface).

A comparison of the subject and predicate device (screws only) is provided in **Table 1** below:

Table 1 Technological characteristic comparison

Parameters	**MectaLIF Anterior Stand Alone Extension (Subject Device)**	**MectaLIF Anterior Stand-Alone K160605 [screws only] (Predicate Device)**
Materials of Construction	Ti-6Al-4V ELI (ISO 5832-3; ASTM F136)	Identical
Sizes (length and diameter)	Diameters: Ø5 and Ø5.5 Lenghts: 25/30/35/40mm (for both the Diameters)	Identical
Tip shape	Aggressive, to facilitate the insertion into the cortical bone	Identical
Head shape	• Length: 3.1 mm • Conical shape; • Hexalobular Socket: Profile according to specifications of ISO 10664	• Length: 2.1 mm • Hexalobular Socket: Torx T20 (according to ISO 10664)
Device usage	Single Use	Identical
Shelf Life	5 years	Identical
Biocompatibility	Implant with permanent contact	Identical
Sterilization	Gamma	Identical
Packaging	Individual packaging	Identical

Discussion

As seen above, the only difference between the subject and predicate device is the new screw head length (longer) and coupling dimension (tighter; Torx Interface), that doesn't introduce any worst case from a clinical point of view or regarding the biomechanical performance of the implants. The new feature has been designed in order to increase instrument coupling stability. This technological difference does not raise new questions of safety or effectiveness when compared to the predicate device(s) and a comparison evaluation shows there are no new risks associated with the subject device design.

Biocompatibility testing conducted on the predicate device MectaLIF Anterior Stand Alone System (K160605) for the same materials to support the biological safety of the MectaLIF Anterior Stand Alone Extension.

VII. Performance Data

The MectaLIF Anterior Stand Alone devices were tested per ASTM F2077-18, ASTM F2267-04 (reapproved 2018), ASTM F1877-05 (reapproved 2010), and ISO 17853:2011 using the worst-case device for each of the following tests:

1. Static Axial Compression
2. Dynamic Axial Compression
3. Static Compression-Shear
4. Dynamic Compression-Shear
5. Static Torsion
6. Dynamic Torsion
7. Subsidence
8. Expulsion

The subject devices do not represent a new worst case when compared to the previously cleared devices (K170455, K160605 and K124034).

The data and information provided in K170455, K160605 and K124034 support the conclusion that the MectaLIF Anterior Stand Alone devices are safe and effective in stand-alone applications when compared to the predicate device(s) and conform to applicable standards and FDA guidance.

VIII. Conclusion

On the basis of the information provided above, the subject devices can be considered as substantially equivalent to the predicate device MectaLIF Anterior Stand Alone System (K160605).

The information provided above supports that the subject MectaLIF Anterior Stand Alone Extension devices are as safe and effective as the predicate device. Therefore, it is concluded that the MectaLIF Anterior Stand Alone Extension implants are substantially equivalent to the predicate device.