DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 16, 2017

Medacta International SA
% Roshana Ahmed
Sr. Manager, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K170455
Trade/Device Name: MectaLIF Anterior Stand Alone
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: February 15, 2017
Received: February 15, 2017

Dear Ms. Ahmed:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170455

Device Name
MectaLIF Anterior Stand Alone

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.

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510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: February 07, 2017

II. Device

Device Proprietary Name:	MectaLIF Anterior Stand Alone
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Regulation Number:	21 CFR 888.3080
Product Code:	OVD
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

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

Reference Device:

- MectaLIF Anterior, K124034, Medacta International SA

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 (ASTM F2026). The spacers are provided uncoated or coated with a commercially pure titanium (CPTi, ASTM F1580) coating. Both uncoated and coated spacers contain tantalum markers (ISO 13782/ASTM F560), and include bone screws made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F136), and a plate made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F136).

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 plates and bone screws were cleared under K124034 and K160605.

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 and the predicate device share the following characteristics:

- Design
- Materials of construction
- Packaging
- Sterilization method

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

- New footprints added to the range of sizes available for the cages
- Lordosis angle in 20 degrees added to the available cages

A comparison of the subject and predicate devices is provided in the table below.

Parameters	**MectaLIF Anterior Stand Alone (Subject Device)**	**MectaLIF Anterior Stand-Alone K160605 (Predicate Device)**
Design/Types	Stand-alone anterior interbody fusion device to be used with bone screws	Identical
Materials of Construction	Cage: PEEK Coating (for coated cages): CPTi Marker: Tantalum	Identical
Cage Footprints (Width x Length x Height)	From 31 x 24 x 10 to 31 x 24 x 18 From 35 x 27 x 10 to 35 x 27 x 18 From 30 x 35 x 10 to 30 x 35 x 18 From 30 x 40 x 10 to 30 x 40 x 18	Min Size: 31 x 24 x 10 Max Size: 35 x 27 x 18
Lordosis	5°, 10°, 15°, 20°	5°, 10°, 15°
Compatibility with implant system	MectaLIF Anterior Stand-Alone system	Identical
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 differences between the subject and predicate devices are the new footprints added to the range of sizes available for the cages and the lordosis angle in 20 degrees added to the available cages. These technological differences do not raise new questions of safety or effectiveness and a comparison evaluation shows there are no new risks associated with the subject device design.

VII. Performance Data

The MectaLIF Anterior Stand Alone devices 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:

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 (K160605 and K124034).

The data and information provided in K160605 and K124034 support the conclusion that the MectaLIF Anterior Stand Alone devices are safe and effective in stand-alone applications and conform to applicable standards and FDA guidance.

VIII. Conclusion

The information provided above supports that the subject MectaLIF Anterior Stand Alone devices are as safe and effective as the predicate device. The addition of new sizes and lordosis angle do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the MectaLIF Anterior Stand Alone is substantially equivalent to the predicate device.

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