DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 21, 2016

Medacta International
% Ms. Roshana Ahmed, RAC
Mapi USA, Incorporated
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K160605
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: June 15, 2016
Received: June 15, 2016

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" (21CFR 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 yours,

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)*
K160605

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

Applicant/Sponsor: 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: Roshana Ahmed, M.A., RAC
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, KY 40504
Sr. Manager, Regulatory Affairs
Phone: 657-248-7361

Date Prepared: June 19, 2016

DEVICE INFORMATION

Trade/Proprietary Name:	MectaLIF Anterior Stand-Alone
Common or Usual Name:	Intervertebral body fusion device
Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Product Code:	OVD
Regulation Number:	888.3080
Device Class:	2

PREDICATE DEVICE INFORMATION

Primary Predicate:

MectaLIF Anterior, K124034, Medacta International SA

Additional Predicates:

MectaLIF TiPEEK, K133192, Medacta International SA
Mecta-C TiPEEK, K142744, Medacta International SA
Vu aPOD, K101310, Theken Spine

DEVICE DESCRIPTION

The MectaLIF Anterior Stand-Alone is a stand-alone anterior interbody fusion device 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 bone screws provided and requires no additional supplementary fixation.

MectaLIF Anterior Stand-Alone consists of disc spacers made of PEEK Implant Grade Polyetheretherketone (ASTM F 2026) body. The spacer is available without any coatings and with a commercially pure titanium (CPTi, ASTM F 1580) coating. Both coated and uncoated spacers contain tantalum markers (ISO 13782 / ASTM F 560), and include bone screws made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F 136), and a plate made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F 136).

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 purpose of this submission is to alter the indications for use, and introduce new plate and screw designs.

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).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The MectaLIF Anterior Stand Alone is identical to the identified predicate devices in terms of cage size footprint, plate sizes, lordosis, screw plate interface, screw sizes, materials of construction, and sterilization method.

PERFORMANCE TESTING

The following tests were conducted on the MectaLIF Anterior Stand-Alone in accordance with ASTM F2077, ASTM F2267, ASTM F1877, and ISO 17853:

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

CONCLUSION:

Based on the information presented above and within the submission, the MectaLIF Anterior Stand Alone is substantially equivalent to the predicate devices.