JAN 30 2014

Medacta International

510(k) Summary

Applicant/Sponsor: Medacta International SA
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Contact Person: Mr. Adam Gross
Director of Regulatory, Quality and Compliance
Medacta USA
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Date Prepared: January 20, 2014

DEVICE INFORMATION

Trade/Proprietary Name: MectaLIF TiPEEK
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR 888.3080
Class II
Device Product Codes: MAX

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K110927	MectaLIF	Medacta International	6/13/2011
K131671	MectaLIF Extension	Medacta International	7/05/2013
K112036	Calix PC Spinal Implant System	X-spine Systems, Inc	11/8/2011

Product Description

MectaLIF TiPEEK is characterized by different sizes of PEEK-OPTIMA LT1 (Polyetheretherketone) implants with a Titanium coating and Tantalum Markers. MectaLIF TiPEEK consists of the Oblique Interbody Fusion Device and Posterior Interbody Fusion Device. The Oblique and Posterior Interbody Fusion Devices are used to replace a degenerative disc in order to restore the height of the spinal column structure. MectaLIF TiPEEK can be applied with common surgical techniques such as PLIF (Posterior Lumbar Intervertebral Fusion) and TLIF (Transforaminal Lumbar Intervertebral Fusion). The devices are intended to be used in combination with posterior fixation (e.g. Pedicle Screw System) as well as an autogenous bone graft. The materials of MectaLIF TiPEEK are as follows: Implant: PEEK-OPTIMA LT1: Implant Grade Polyetheretherketone (ASTM F 2026) with commercially pure titanium (CPTi, ASTM F 1580) coating and Marker: Tantalum (ISO 13782 / ASTM F 560).

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.

Comparison to Predicate Devices

MectaLIF TiPEEK is identical to the implants cleared under K110927 and K131671 except for the addition of the commercially pure titanium (CPTi, ASTM F 1580) coating, which is the same coating used with K112036 Calix PC. The indications for use of MectaLIF TiPEEK are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The substantial equivalence of the MectaLIF TiPEEK implants are supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

Performance Testing

Performance testing was conducted in accordance with FDA Guidance - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device as well as in accordance with FDA Guidance - Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements. Additional wear analysis for particulates was conducted and it was determined that MectaLIF TiPEEK passed all requirements.

MectaLIF TiPEEK was tested using the worst-case device for each of the following tests:

Static and dynamic axial compression - ASTM F2077
Static and dynamic shear compression - ASTM F2077
Subsidence - ASTM F 2267
Wear Analysis - ASTM F2077, ASTM F1877
Abrasion resistance - ASTM F1978
Static Tensile strength - ASTM F1147
Static Shear strength - ASTM F1044
Shear fatigue strength - ASTM F1160
Micrographical Analysis - ASTM F1854

Conclusion:
Based on the above information, the MectaLIF TiPEEK can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 30, 2014

Medacta International
Mr. Adam Gross
Director of Regulatory, Quality and Compliance
Medacta USA
1556 West Carroll Avenue
Chicago, Illinois 60607

Re: K133192
Trade/Device Name: MectaLIF TiPEEK
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 18, 2013
Received: November 14, 2013

Dear Mr. Gross:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Vincent D. Devlin -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 on last page.

510(k) Number *(if known)*
K133192

Device Name
MectaLIF TiPEEK

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
FDA
Division of Orthopedic Devices

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