K120024

FEB 28 2012

Medacta International

510(k) Summary

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Date Prepared: December 30, 2011

DEVICE INFORMATION

Trade/Proprietary Name: MectaLIF Transforaminal
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: K110927 MectaLIF Oblique (Medacta Intl)
K040536 Verte-Stack Boomerang (Medtronic)
K072791 OPAL Spacer (Synthes)
K081888 Dynamik (Spineart)
K081917 Devex/Leopard (Depuy Spine)
P960025 Lumbar IF Cage (Depuy Acromed)
K103034 Apache TLIF (Genesys Spine)

K120024

Product Description

MectaLIF Transforaminal lumbar intervertebral body fusion device is characterized by different sizes of PEEK-OPTIMA LT1 (Polyetheretherketone) implants that can be applied with a TLIF procedure (Transforaminal Lumbar Intervertebral Fusion). MectaLIF Transforaminal is used to replace a degenerative disc in order to restore the height of the spinal column structure. They are made of PEEK-OPTIMA LT1 and contain Tantalum Markers as well as a titanium gear which enables the surgeon to alter the angle of the MectaLIF Transforaminal in situ in 15° increments and to reposition during surgery without switching instrumentation. MectaLIF Transforaminal is intended to be used in combination with posterior fixation (e.g. Pedicle Screw System) as well as an autogenous bone graft. The dimensions of MectaLIF Transforaminal are within the following range: Length 30-34mm; Height 8-15mm; Width 12-14mm; Lordosis 5°. The materials of the components of MectaLIF Transforaminal are as follows: Implant: PEEK-OPTIMA LT1: Implant Grade Polyetheretherketone (ASTM F 2026), Gear: Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F 136), 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 Transforaminal is substantially equivalent in terms of indications for use, material, design, and performance characteristics as the previously cleared K110927 MectaLIF Oblique (Medacta Intl), K040536 Verte-Stack Boomerang (Medtronic), K072791 OPAL Spacer (Synthes), K081888 Dynamik (Spineart), K081917 Devex/Leopard (Depuy Spine), P960025 Lumbar IF Cage (Depuy Acromed), and K103034 Apache TLIF (Genesys Spine).

Performance Testing

MectaLIF Transforaminal has similar performance testing as the predicates in terms of:

Static Axial Compression - ASTM F2077
Dynamic Axial Compression - ASTM F2077
Static Compression/Shear - ASTM F2077
Dynamic Compression/Shear - ASTM F2077
Subsidence Resistance - ASTM F2267

Conclusion:
Based on the above information, MectaLIF Transforaminal can be considered as substantially equivalent to its predicate devices in terms of indications for use, material, design, and performance characteristics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Re: K120024
Trade/Device Name: MectaLIF Transforaminal
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 31, 2012
Received: February 01, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120024

Indications for Use

510(k) Number (if known):

Device Name: MectaLIF Transforaminal

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.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120024

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