DEC 19 2011

Medacta International

510(k) Summary

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Contact Person: Mr. Adam Gross
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Date Prepared: September 30, 2011

DEVICE INFORMATION

Trade/Proprietary Name: Mecta-C
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Body Fusion Device, Cervical

21 CFR 888.3080
Class II
Device Product Codes: ODP

Predicate Devices: K101363 Theken Spine Vu cPOD
P980048 Centerpulse Spine-Tech BAK-C
K081917 Depuy Spine Bengal Cage
K110927 Medacta MectaLIF
K083311 Aesculap CeSpace
K073177 Pioneer Intervertebral Body Fusion System
K100889 - Titan Spine Endoskeleton TC

Product Description

The Mecta-C Intervertebral Body Fusion Devices are fusion devices intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine. The Mecta-C body fusion device is indicated for the treatment of degenerative diseases of the cervical disc and can be used for cervical fusion from C2-T1. The Mecta-C intervertebral body fusion devices consist of a PEEK (Polyetheretherketone) body and tantalum markers. The markers are placed in the implant on each end of the PEEK cages to allow easier radiological assessment of the position and orientation of the radiolucent PEEK cages. The cages are offered in various widths, heights, footprint geometries and lordosis which can be inserted between two cervical vertebra bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Indications for Use

The Mecta-C intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.

The Mecta-C device is intended for use at one level in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment prior to treatment with the device.

Comparison to Predicate Devices

The Mecta-C Intervertebral Body Fusion Device is substantially equivalent to K101363 Theken Spine Vu cPOD, P980048 Centerpulse Spine-Tech BAK-C, K083311 Aesculap CeSpace, K073177 Pioneer Intervertebral Body Fusion System, K100889 Titan Spine Endoskeleton TC, and K081917 Depuy Spine Bengal Cage in terms of indications for use, design, and function. Mecta-C is also substantially equivalent to K110927 Medacta MectaLIF, Vu crPOD and Bengal Cage in terms of materials. Mecta-C is substantially equivalent to MectaLIF in the manufacturing process. Performance testing has demonstrated that the Mecta-C Intervertebral Body Fusion Device is substantially equivalent in mechanical performance to the Vu cPOD and the Bengal Cage in Static and Dynamic Compression, Compression/Shear, Torsion, and Subsidence performance.

Performance Testing

Similar Static Axial Compression - ASTM F2077
Similar Dynamic Axial Compression - ASTM F2077
Similar Static Compression/Shear - ASTM F2077
Similar Dynamic Compression/Shear - ASTM F2077
Similar Static Torsion - ASTM F2077
Similar Dynamic Torsion - ASTM F2077
Similar Subsidence - ASTM F2267

Conclusion:
Based on the above information, the Mecta-C Intervertebral Body Fusion Device can be considered as substantially equivalent to its predicate devices in regards to indications, intended use, and technological features.

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

Medacta International SA
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Mr. Adam Gross
Director of Regulatory and Quality
4725 Calle Quetzal, Unit B
Camarillo, California 93012

DEC 19 2011

Re: K112862
Trade Name: Mecta-C
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 17, 2011
Received: November 18, 2011

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,

For

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

Enclosure

Indications for Use

510(k) Number (if known): K112862

Device Name: Mecta-C

Indications for Use:

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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 K112862