K091967

MAR - 2 2010

Medacta International

510(k) Summary

Manufacturer: MEDACTA International SA
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Contact Person: Ms. Natalie J. Kennel
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Date Prepared: June 26, 2009

DEVICE INFORMATION

Trade/Proprietary Name: Medacta® Bipolar Heads

Common Name: Hemi-hip prosthesis, uncemented
Classification Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
21 CFR 888.3390
Class II
Device Product Code: KWY

Predicate Devices: K082468 Apex Hip System Bipolar Head
K050966 Ortho Development Pivot Bipolar Head
K014072 Disc-O-Tech Medical Technologies Ltd's Fixion™ Unipolar Modular Hemi-Hip System
K982447 Plus Orthopedics PLUS Bipolar Heads

Product Description:
The Medacta® Bipolar Head consists of a factory assembled Ultra High Molecular Weight Polyethylene (UHMWPE) liner in an outer shell of stainless steel, designed to articulate directly in the patient's actebulum. The inner liner of UHMWPE articulates the prosthetic femoral head. The prosthetic femoral head is locked into place with an elastic retaining ring. The Medacta® Bipolar Head is available in outer diameters from 40 mm to 52 mm in 1 mm increments with an inner diameter that mates with a 22 mm diameter femoral head. The Medacta® Bipolar Head is also available in outer diameters from 44 mm to 60 mm in 2 mm increments with an inner diameter that mates with a 28 mm diameter femoral head. The Medacta® Bipolar Head may be used for hemiarthroplasty in conjunction with the following femoral stems which are part of the Medacta® Hip Prosthesis System – Quadra S, Quadra H and Quadra R stems. (K072857, K082792) The Medacta® Bipolar Heads may be used with the following femoral heads which are part of the Medacta® Hip Prosthesis System – CoCrMo femoral heads - and the ceramic femoral heads called the Mectacer Femoral Heads. (K073337, K080885).

The Medacta® Bipolar Head is a product suitable to use in a hemiarthroplasty procedure on any hip joint whose acetabular conditions are satisfactory.

Indications for Use:
The Medacta® Bipolar Head is intended for use in combination with Medacta® Hip Prosthesis System and Mectacer femoral heads for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

Comparison to Predicate Devices
The Medacta® Bipolar Heads have the same indications for use as the predicate, Apex Hip System Bipolar Head (K082468) except for the specific femoral stems and heads with which it works. Medacta® Bipolar Heads are very similar in design, size range, and functionality as all of the bipolar predicates: Apex Hip System Bipolar Head, Ortho Development Pivot Bipolar Head (K050966) and Plus Orthopedics Bipolar Heads (K982447). They all are factory assembled with an UHMWPE liner which is not highly crosslinked. The Medacta® Bipolar Heads' outer metal shell, which is made of stainless steel, is the same type of material used in direct articulation with the natural acetubulum as the Disc-O-Tech Medical Technologies Ltd's Fixion™ Unipolar Modular Hemi-Hip System. Although the Disc-O-Tech predicate device is a unipolar head instead of bipolar head, the Medacta® Bipolar Heads have very similar indication for use as the Disc-O-Tech predicate device.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the Medacta® Bipolar Head was conducted in accordance with various international standards and FDA guidance documents.

The Medacta® Bipolar Head was tested as part of design verification to written protocols with pre-defined acceptance criteria. The testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that the performance of the Medacta® Bipolar Head is substantially equivalent to the predicate devices.

Conclusion:

The data and information provided in this submission support the conclusion that the Medacta® Bipolar Head is substantially equivalent to its predicate devices, Apex Hip System Bipolar Head, Ortho Development Pivot Bipolar Head and Plus Orthopedics Bipolar Head with respect to intended use, design, and operational principles. The Medacta® Bipolar Head is substantially equivalent to its predicate, the Disc-O-Tech Medical Technologies Ltd's Fixion™ Unipolar Modular HemiHip System with respect to its outer shell material and tribological effect.

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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Re: K091967
Trade/Device Name: Medacta Bipolar Heads
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: January 25, 2010
Received: January 28, 2010

Dear Ms. Kennel:

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.

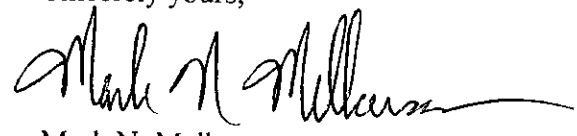
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use Statement

510(k) Number (if known): K091967

Device Name: Medacta® Bipolar Heads

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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