Medacta International

MAR 2 1 2011

510(k) Summary

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Date Prepared: March 17, 2011

DEVICE INFORMATION

Trade/Proprietary Name: Mpact® Acetabular System
Medacta 40 mm Ball heads

Common Name: Total Hip Acetabular Components
Femoral ball heads

Classification Name: 21 CFR 888.3358 Hip joint, femoral metal/ polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Product Code: LPH
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Product Code: LZO
Class II

Predicates: K071784 DePuy Pinnacle® with Gription™ Acetabular Cups
K001534 Pinnacle Acetabular System, DePuy Orthopedics
K070756 REFLECTION 3 Acetabular System, Smith & Nephew
K101575 Apex Modular Heads, +10.5 mm offset, Omni Lifesciences
K100555 Apex- LNK Poly Acetabular Liners and Apex Modular Head, 40 mm, Omni Lifesciences
K083116 Versafitcup® Double Mobility, Medacta International
K092265 Versafitcup® Double Mobility HighCross® UHMWPE Liners, Medacta International
K091069 Medacta Bone Screws, Medacta International
K072857 Medacta Total Hip Prosthesis, Medacta International
K080885 Medacta Total Hip Prosthesis CoCrMo ball heads, Medacta International

Product Description:

The Mpact® Acetabular System components are designed to be used with the Medacta Total Hip Prosthesis System. The Medacta Total Hip Prosthesis system includes the Quadra S, H, R, and C Stems and CoCrMo and ceramic ball heads (K072857, K073337, K080885, K082792, and K083558). The AMIStem femoral stems also work with the Medacta Total Hip Prosthesis System (K093944). The Medacta Total Hip Prosthesis System is a total hip replacement system consisting of the femoral stem made of metal, a modular femoral head made of metal or ceramic, and acetabular components. The Mpact® Acetabular System acetabular components that are the subject of this 510(k) consist of a metal cup made of Titanium alloy and a fixed liner that is made of ultra-high molecular weight polyethylene (UHMWPE) or HighCross® highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE).

The metal acetabular component or shell is machined from titanium alloy (Ti-6Al-4V) conforming to ISO 5832-3 and ASTM F136. The outside of the metal component is a hemispherical design. The outer surface of the metallic cup has a porous coating called TiGrowth made of pure titanium conforming to ASTM F1580. The polyethylene liner is a fixed liner made of UHMWPE conforming to ISO 5834-2. The liner has a minimum thickness of at least 5.5 mm when made of standard UHMWPE and of least 4 mm when made of HXUHMWPE.

If supplemental bone screw fixation is needed, cancellous bone screws made of titanium alloy (Ti-6Al-4V) can be inserted through screw holes. Screw hole covers made of titanium alloy (Ti-6Al-4V) are also provided for the central hole.

Also included in this submission are additional Medacta ball heads made of CoCrMo in the 40 mm diameter to augment the Medacta ball heads previously cleared in K072857, K073337 and K080885.

The metal acetabular component is available in 11 sizes and is for use with

polyethylene liners that accept both CoCrMo with diameters of 22, 28, 32, and 36 mm and MectaCer BIOLOX® *forte* Ceramic ball heads with diameters of 28, 32, and 36 mm. They also work with the Medacta 40 mm CoCrMo ball heads. The fixed liners are available in both flat and hooded options in a range of sizes.

All the Mpact® Acetabular System components and Medacta 40 mm ball heads are supplied sterile in single-use individual packages.

Indications for Use:
The hip prosthesis is designed for cementless use in total hip arthroplasty in primary or revision surgery.

The patient should be skeletally mature.

The patient's condition should be due to one or more of:

- Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriatic arthritis, Congenital hip dysplasia, ankylosing spondylitis.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.

Wear Claim
Medacta's Mpact® liners are made of HighCross™ highly crosslinked UHMWPE (ETO sterilized). The UHMWPE raw material, used for HighCross™ UHMWPE, is Chirulen 1020. The HighCross™ UHMWPE liners were gamma irradiated at 100 kGy and thermally stabilized at 150°C with controlled cooling, to optimize the crystallinity of the material. The liners were manufactured by turning compression molded UHMWPE bars and were finished products that followed all the manufacturing process flow including final sterilization.

The Mpact® liners tested were 4 mm thick, size Ø40/F. Testing was conducted under a multi-axial hip joint simulation with a standard walking gait cycle as specified by ISO 14242-1 with a 3.4 kN peak load for 5 million cycles using a 40 mm size M CoCrMo ball head and metal acetabular shell of size 54 mm. The lubricant was composed of calf serum with a 30 g/L protein content and deionized water. EDTA and Patricin were added to bind the calcium phosphate and to retard bacteria-induced degradation, respectively. The lubricant was filtered before doing the test and maintained at 37°C. The lubricant was replaced every 0.5 million cycles. Three liners were tested. Wear was measured at 0.5, 1, 2, 3, 4 and 5 million cycles.

Average gravimetric and volumetric wear rates were 6.28 mg +/- 1.68 mg per million cycles and 6.75 mm^3 +/- 1.8 mm^3 per million cycles, respectively, for the Mpact® HighCross™ UHMWPE liners. The average total wear for 5 million cycles was 31.54 mg for the 40 mm inner diameter liners.

The in vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance. Also, a reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of this wear claim.

Comparison to Predicate Devices

The Mpact® Acetabular System family is similar to the DePuy Pinnacle® with Gription™ Acetabular Cups and the Smith & Nephew REFLECTION 3 Acetabular system in indications for use, design, materials, coating, and technological characteristics. The bone screws are similar to the Medacta Bone Screws in materials and design. The standard UHMWPE liners are made of the same material and process as the Versafitcup® Double Mobility standard UHMWPE liners. The HighCross® highly crosslinked UHMWPE liners of the Mpact® Acetabular System is the same HighCross® highly crosslinked UHMWPE of which the Versafitcup® Double Mobility HighCross® UHMWPE liners are made. The Medacta 40 mm ball heads are similar to Apex Modular heads in indications for use, material, size and options. The Medacta 40 mm ball heads have the same indications for use, material, design, and performance characteristics as the previously cleared CoCrMo ball heads in the Medacta Total Hip Prosthesis System.

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 Mpact® Acetabular System was conducted in accordance with various international standards and FDA guidance documents.

The Mpact® Acetabular System and Medacta 40 mm ball heads were tested as part of design verification to written protocols with pre-defined acceptance criteria. The Mpact® testing was conducted on the worst case component size and option/design. The design verification testing included push out, lever out and rotational stability of the modular connection of the fixed liner to the metal shell, coating validation, metal shell deformation resistance during impaction, range of motion, wear, and bone screw testing. The Medacta 40 mm ball heads testing were included in the worst case testing of the previously cleared ball heads. The testing met all acceptance criteria and verifies that the performance of the Mpact® Acetabular System and Medacta 40 mm ball heads are substantially equivalent to the predicate devices.

Conclusion:

The data and information provided in this submission support the conclusion that the Mpact® Acetabular System and Medacta 40 mm ball head are substantially equivalent to its main predicates devices: DePuy Pinnacle® with Gription® Acetabular Cups and Smith & Nephew REFLECTION 3 Acetabular System with respect to indications for use and technological characteristics. The Mpact® Acetabular System is also substantially equivalent to the Medacta Bone Screws and Versafitcup® Double Mobility and Versafitcup® Double Mobility HighCross® Liners for various technological characteristics. The Medacta 40 mm ball heads are

substantially equivalent to the Apex Modular heads and the Medacta Total Hip Prosthesis CoCrMo ball heads with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Medacta International SA
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Ms. Natalie J. Kennel
13721 Via Tres Vista
San Diego, California 92129

MAR 2 1 2011

Re: K103721
Trade/Device Name: Mpact® Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO
Dated: December 14, 2010
Received: December 21, 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,

For Mark N. Melkerson

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

Enclosure

K103721

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Indications for Use Statement

510(k) Number (if known):

Device Name: Mpact® Acetabular System

Indications for Use:

The Mpact® Acetabular System is intended for cementless use in total hip arthroplasty and in primary or revision surgery. The patient should be skeletally mature. The patient's condition should be due to one or more of:

- Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic arthritis, congenital hip dysplasia, or ankylosing spondylitis.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.

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)

for M. Nielkerson

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

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