K112115

OCT - 7 2011

Medacta International

510(k) Summary

Manufacturer: Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
FAX (+41) 91 696 60 66

Contact Person: Adam Gross
Director of Regulatory and Quality
Medacta USA
4725 Calle Quetzal, Unit B
Camarillo, CA, 93012
Phone: (805)437-7085
Fax: (805)437-7553
Email: AGross@medacta.us.com

Date Prepared: July 21, 2011

DEVICE INFORMATION

Trade/Proprietary Name: Mectacer Biolox Delta Heads
Common Name: Femoral Heads
Classification Name: Hip Joint, metal/ceramic/polymer, semiconstrained, cemented or non-porous uncemented prosthesis

21 CFR 888.3353
Class II
Device Product Code: LZO

Predicate Devices:
K073337 Medacta MectaCer BIOLOX® forte Femoral Heads
K071535 Zimmer BIOLOX delta Ceramic Femoral Head
K083762 Smith & Nephew Biolox Delta Ceramic Femoral Heads
K100412 Smith & Nephew Biolox Delta Ceramic Femoral Heads - large sizes

Product Description

The MectaCer Biolox Delta Heads are ceramic ball heads intended for mechanical fixation to a mating hip stem and indicated for the treatment of patients who are candidates for total or partial hip arthroplasty to provide increased patient mobility and reduced pain by replacing the damaged hip joint, in primary or revision surgery.
The MectaCer Biolox Delta Heads are an aluminum oxide matrix composite ceramic consisting of approximately 75% alumina (Al_2O_3), 24% zirconia (ZrO_2) and other trace elements. The pink color is due to the chromium oxide (Cr_2O_3) that improves the hardness of the composite material. The MectaCer Biolox Delta Heads are designed to mate with a 12/14 stem taper. The MectaCer Biolox Delta Heads are available in head diameters of 28, 32, 36, 40, and 44 mm and in neck lengths of Small, Medium, Large, and Extra Large.

Indications for Use

The MectaCer BIOLOX® *forte* femoral heads and the MectaCer BIOLOX® *delta* femoral heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for total or partial 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 the following:

- 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.

Comparison to Predicate Devices

The MectaCer Biolox Delta Heads are substantially equivalent to K073337 Medacta MectaCer BIOLOX® forte Femoral Heads, K071535 Zimmer BIOLOX delta Ceramic Femoral Head, K083762 Smith & Nephew Biolox Delta Ceramic Femoral Heads, and K100412 Smith & Nephew Biolox Delta Ceramic Femoral Heads - large sizes. The MectaCer Biolox Delta Heads have the same indications for use as the MectaCer Forte Femoral Heads. The MectaCer Biolox Delta Heads have the same material as the Biolox Delta Heads cleared under K071535, K083762, and K100412. The MectaCer Biolox Delta Heads have the same head diameters as all of the predicate devices (28,32,36mm of the MectaCer Forte Heads; 28,32,36,40mm of the Zimmer Delta Heads; and 28,32,36,40,44mm of the Smith & Nephew Delta Heads). The MectaCer

Biolox Delta Heads have the same neck lengths (S, M, L) as all of the predicate devices and also have the same XL neck length as the Zimmer Biolox Delta Heads.

Performance Testing

The MectaCer Biolox Delta and Forte Heads were tested as part of design verification to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on standards and FDA guidance. The testing was conducted on the worst case size MectaCer Biolox Delta and Forte Heads. The test on the Ti6Al7NB (ISO 5832-11) taper covers compatibility with Medacta's Quadra S (K072857), Quadra H (K082792), Quadra R (K082792), Quadra S-H/SN (K093944), and AMIStem H (K093944) femoral stems. The test on the High Nitrogen Stainless Steel (ISO 5832-9) taper covers compatibility with Medacta's Quadra C (K083558), Quadra C SN (K103189), and AMIStem C (K103189) femoral stems. The testing met all acceptance criteria and verifies that the performance of the MectaCer Biolox Delta Femoral Heads would be adequate for anticipated in vivo loading and that the MectaCer Biolox Forte Heads remain worst-case in comparison to the MectaCer Biolox Delta Heads.

The **Burst Test** was a compression test made under smooth load with a constant rate of 2mm/min according to ISO 7206-10 (ISO 7206-10: Implants for surgery – Partial and total hip joint prostheses – Part 10: Determination of resistance to static load of femoral heads). The ball is placed on a conical bearing simulating the stem. The modular connection between the ball and the stem of a hip prosthesis is loaded until failure.

The **Fatigue Test** was made according to CeramTec test procedure AA 02 10 0807. The ball is placed on a conical bearing simulating the stem. The modular connection between the ball and the stem of a hip prosthesis is loaded with a sinusoidal axial force at 10 million cycles.

The **Post-Fatigue Test** was a compression test made under smooth load with a constant rate of 2mm/min according to ISO 7206-10 (ISO 7206-10: Implants for surgery – Partial and total hip joint prostheses – Part 10: Determination of resistance to static load of femoral heads). The modular connection between the ball and the stem of a hip prosthesis is loaded until failure after the fatigue test.

The **Rotational Stability Test** or "torsion test" followed the test description according to the Ceramtec procedure VP-KU-0180. A modular fitting between ball and stem is subjected to frictional torsion until movement occurs.

The **Pull-Off Test** was made in compliance with the test description of the CeramTec procedure VP-KU-0210, but with 5 samples according to the FDA recommendations. This test corresponds to ISO 7206-10. The femoral head is pressed onto a taper using an axial force of 2 kN and pulled off axially using a loading rate of 1mm/min.

A review of the mechanical data indicates that the MectaCer Biolox Delta Heads are equivalent to devices currently cleared for use and are capable of withstanding expected in vivo loading without failure.

Conclusion:
Based on the above information, the MectaCer Biolox Delta Heads 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

OCT - 7 2011

Re: K112115
Trade/Device Name: MectaCer Biolox Delta Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: September 20, 2011
Received: September 21, 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): K112115

Device Name: Mectacer Biolox Delta Heads

Indications for Use:

The MectaCer BIOLOX® *forte* femoral heads and the MectaCer BIOLOX® *delta* femoral heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for total or partial 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 the following:

- 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.

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 K112115