Medacta International

510(k) Summary

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OCT 0 1 2013

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Date Prepared: May 17, 2013

DEVICE INFORMATION

Trade/Proprietary Name: Mpact DM Converter
Common Name: Total Hip Acetabular Components
Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

21 CFR 888.3353
Class II
Device Product Codes: LZO, MEH

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance
K103721	Mpact Acetabular System	Medacta International	3/21/2011
K122641	Mpact Extension	Medacta International	9/28/2012
K083116	Versafitcup Double Mobility	Medacta International	4/7/2009
K092265	Versafitcup Double Mobility Highcross Liners	Medacta International	3/12/2010
K103233	MDM	Stryker	2/3/2011

Product Description

The Mpact DM Converter is a highly polished CoCrMo (ASTM F1537) liner with a tapered locking mechanism which assures the connection with the acetabular shell. The Mpact DM Converter can only be coupled with Medacta Double Mobility UHMWPE (ISO 5834-2 Type 1) liners (K083116) or HighCross® highly crosslinked UHMWPE liners (K092265) and can only be used with Mpact Primary (K103721) or Mpact Extension (K122641) acetabular shells.
The Mpact DM Converter has a 5° shoulder which increases the jump distance and it also has a small tooth which can be used in case of revision to extract the liner.
The six available sizes have a nomenclature that identifies the cup liner size (first letter) and the double mobility liner size (final three letters): D/DMB, E/DMC, F/DME, G/DMF, J/DMH and K/DML.

This submission also includes one new size (22.2/DMB) of the Medacta Double Mobility liner in both UHMWPE (ISO 5834-2 Type 1) and HighCross® highly crosslinked UHMWPE. These liners are identical to the liners in the K083116 and K092265 submissions but have a smaller external diameter than the predicates. These new liners can only be coupled with a 22.2mm ball head and have a minimum thickness of 5 mm.

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, posttraumatic 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

Mpact DM Converter 510(k)

The indications for use of the Mpact DM Converter are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the Mpact DM Converter are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The Mpact Extension was tested as part of design verification to written protocols with pre-defined acceptance criteria. The Mpact DM Converter testing was conducted on the worst case component size and option/design. The Mpact DM Converter was tested for range of motion, pull-off, push-out, lever-out, torsion, wear, fretting corrosion, and jump distance.
The comparison to predicate devices and the mechanical testing performed demonstrate that the Mpact DM Converter is substantially equivalent.

Conclusion:
Based on the above information, the Mpact DM Converter 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 Center - WO66-G609
Silver Spring, MD 20993-0002

October 1, 2013

Medacta International
% Mr. Adam Gross
Medacta USA
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K131458
Trade/Device Name: Mpact DM Converter
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: July 2, 2013
Received: July 3, 2013

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 contact 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. 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,

Erin D Keith

for

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

Enclosure

Indications for Use

510(k) Number (if known): K131458

Device Name: Mpact DM Converter

Indications for Use:

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

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- Severely painful and/or disabled joint: as a result of osteoarthritis, posttraumatic 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices