K083558 #1/3

MAR 6 2009

Medacta International

Traditional 510(k) Summary

Manufacturer: MEDACTA International SA
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Contact Person: Ms. Natalie J. Kennel
Consultant
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Date Prepared: Feb. 23, 2009

DEVICE INFORMATION

Trade/Proprietary Name: Medacta Total Hip Prosthesis – Quadra C femoral stems

Common/Classification Name: Hip Joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
21 CFR 888.3353
Class II
Device Product Code: LZO, JDI

Predicate Devices: Medata Total Hip Prosthesis – Quadra S femoral stems, K072857, cleared on Feb. 4, 2008
Sulzer Orthopedics MS-30 Femoral Stem, K993043, cleared on Dec. 2, 1999
Sulzer Orthopedics MS-30 Lateral Femoral Stems, K020713, cleared on May 14, 2002

K083558 #2/3

Product Description:
The Medacta Total Hip Prosthesis System – Quadra C femoral stem is a highly polished, collarless femoral component manufactured from forged stainless steel according to ISO 5832-9. The Quadra C femoral stem is a straight quadratic stem with a triple taper shape. The Quadra C femoral stems come in eight sizes with a standard offset and seven sizes with a lateral offset. The proximal portion of the stem has a standard 12/14 taper for mechanical attachment to cleared Medacta International metallic or ceramic femoral heads.

Indications for Use:
The Medacta Total Hip Prosthesis System- Quadra C femoral stems are intended for cemented use in total or partial hip arthroplasty and in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia
- 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.

Size 0 implants should not be implanted in patients with a mass of 65 kg or greater.

Comparison to Predicate Device:
The Medacta Total Hip Prosthesis – Quadra C femoral stems are similar in intended use, materials and general design to the Sulzer Orthopedics MS-30 standard and lateral femoral stems. The Quadra C femoral stems are intended for cemented use only and are manufactured from forged stainless steel according to ISO 5832-9, the same as the MS-30. The general shape, design, and 12/14 taper of the Quadra C femoral stems is the same as the MS-30 femoral stems.

The Quadra C femoral stems are essentially identical to their other predicate, Quadra S femoral stems, in terms of shape and dimensions. The Quadra C femoral stems have the identical neck, taper, length and offset. The Quadra C femoral stems come in a subset of sizes that are identical to the Quadra S in terms of length and shape except that they have a smooth highly polished surface instead of the macrostructures on the Quadra S with its sandblasted surface. The Quadra C femoral stems work with the same range of ball heads cleared under the original Medacta Total Prosthesis System – Quadra

K083558 #3/3

S, K072857, and subsequent submissions for the MectaCer Ceramic ball heads, K073337, and for additional CoCrMo ball heads sizes, K080885. The Quadra C femoral stems with these ball heads work with the Ortho Development's Triplus® Acetubular cups and liners. They can also be used with Medacta CoCrMo femoral ball heads of sizes 22 and 28 and the Ortho Development's Pivot Bipolar heads. These system compatibilities are the same as the predicate device, Quadra S femoral stems.

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 Quadra C femoral stems was conducted in accordance with various international standards and FDA guidance documents.

The Quadra C femoral stems 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 the international standards and FDA guidance. 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 Total Hip Prosthesis- Quadra C femoral stems are substantially equivalent to the predicate devices.

Conclusion:

The data and information provided in this submission support the conclusion that the Medacta Total Hip Prosthesis System – Quadra C femoral stems are substantially equivalent to their predicates, Sulzer Orthopedics MS-30 standard and lateral femoral stems and Medacta Total Hip Prosthesis System – Quadra S femoral stems, with respect to intended use, materials, design and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2009

Medacta International, SA
% NJK & Associates, Inc.
Ms. Natalie J. Kennel
13721 Via Tres Vista
San Diego, California 92129

Re: K083558
Trade/Device Name: Medacta Total Hip Prosthesis System – Quadra C Femoral Stems
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, JDI
Dated: February 18, 2009
Received: February 20, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

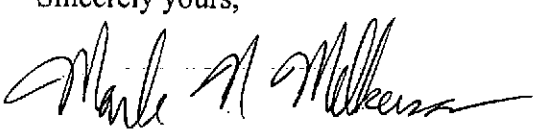
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K083558

Device Name: Medacta Total Hip Prosthesis System – Quadra C Femoral Stems

Indications for Use:

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Size 0 implants should not be implanted in patients with a mass of 65 kg or greater.

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)

(Division S... Off)
Division of General, Restorative, and Neurological Devices

Page __ of ___

510(k) Number K083558