K103189 (pg 1/3)

Medacta International

510(k) Summary

DEC 2 0 2010

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Date Prepared: October 25, 2010

DEVICE INFORMATION

Trade/Proprietary Name: AMIStem C & Quadra C SN femoral stems
Common Name /Classification Name: Hip joint, femoral metal/ ceramic, polymer semi-constrained metallic cemented or uncemented prosthesis

21 CFR 888.3360
Class II
Device Product Code: LZO, JDI

Predicate Devices: Medacta Total Hip Prosthesis system – Quadra C, Medacta International cleared under K083558.

Product Description:
This modification to the original Medacta Total Hip Prosthesis System – Quadra C femoral stems is a line extension to include the AMIStem C femoral stems and Quadra C Short Neck (SN) femoral stems. AMIStem C femoral

stems are based on the design of the Quadra C femoral stems in the original submission. The AMIStem C femoral stems differ from the Quadra C femoral stems by a decreased length of 15% and a reduced shoulder. The Quadra C short neck femoral stems are the same design femoral stems as the Quadra C femoral stems in the original submission but the length of the neck that is 5 mm shorter.

Like the Quadra C femoral stems, the AMIStem C femoral stems and the Quadra C SN femoral stems are highly polished, collarless femoral components manufactured from forged stainless steel according to ISO 5832-9. The AMIStem C femoral stems and the Quadra C SN femoral stems are straight quadratic stems with a triple taper shape. The proximal portion of the stem has a standard 12/14 taper for mechanical attachment to cleared Medacta International metallic or ceramic femoral heads.

Like the Quadra C femoral stems, two different caput-collum-diaphyseal angles (CCD) are available for the AMIStem C femoral stems and the Quadra C Short neck femoral stems: 135° for the standard offset and 127° for the lateralized offset. The Quadra C short neck femoral stems come in eight sizes with a standard offset and seven sizes with a lateral offset. The AMIStem C femoral stems come in eight sizes with a standard offset and seven sizes with a lateral offset. There are no short neck versions for the AMIStem C femoral stems.

The AMIStem C femoral stems and the Quadra C short neck femoral stems provide additional femoral stem options to the surgeon for use with the Medacta Total Hip Prosthesis System.

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 Devices:

The Medacta Total Hip Prosthesis System- AMIStem C femoral stems and Quadra C short neck femoral stems are substantially equivalent to the Medacta Total Hip Prosthesis system – Quadra C, cleared under K083558.

The AMIStem C femoral stems and the Quadra C short neck femoral stems are made of the same materials as the Quadra C femoral stems in the predicate device. They have the same general design as the Quadra C femoral stems. They have the same compatibilities as the Quadra C 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 AMIStem C and Quadra C Short neck femoral stems was conducted in accordance with various standards and FDA guidance documents. A detailed list is provided in Section 18 Performance Testing – Bench.

The modifications to the device system to include the addition of AMIStem C and Quadra C short neck femoral stems were evaluated by risk analysis to identify any new risks associated with these changes. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards and FDA guidance. The testing was conducted on the worst case based on engineering analysis. The testing included endurance testing of the neck and stem regions of the femoral components as well as range of motion analysis. The design verification activities met all acceptance criteria and verified the performance of the Medacta Total Hip Prosthesis System – AMIStem C femoral stems and Quadra C short neck femoral stems.

Conclusion:

The results from the design control activities and the information provided in this submission support the conclusion that the Medacta Total Hip Prosthesis system – AMIStem C femoral stems and Quadra C short neck femoral stems are substantially equivalent to its predicate device, Medacta Total Hip Prosthesis Quadra C femoral stems with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medacta International SA
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DEC 20 2010

Re: K0103189
Trade/Device Name: Medacta Total Hip Prosthesis – AMIStem C, Quadra C SN
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI
Dated: November 30, 2010
Received: December 1, 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

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): K103189 (pg 1/1)

Device Name: AMIStem C & Quadra C SN

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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)

for M. Melkerson

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

510(k) Number K103189