



DEC 29 2008

Special 510(k) Summary

Manufacturer: MEDACTA International SA
Strada Regina
CH6874 Castel San Pietro
Switzerland
Phone (+41) 91 696 60 60
FAX (+41) 91 696 60 66

Contact Person: Ms. Natalie J. Kennel
Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, CA 92129 USA
Phone: (858) 705-0350
Fax: (858) 764-9739
email: NKennel@njconsulting.com

Date Prepared: Nov. 26, 2008

DEVICE INFORMATION

Trade/Proprietary Name: Medacta Total Hip Prosthesis – Quadra H, Quadra R femoral stems

Common/Classification Name: Hip Joint, metal/polymer/metal semi-constrained cemented prosthesis

21 CFR 888.3350

Class II

Device Product Code: JDI

Predicate Device: Medacta Total Hip Prosthesis – Quadra S femoral stems, K072857, cleared on Feb. 4, 2008

Product Description:

The modifications to the original Medacta Total Hip Prosthesis system are a line extension to include the Quadra H and Quadra R femoral stems. The Quadra H femoral stems are the same design femoral stems as the Quadra S femoral stems in the original submission but with the application of a

hydroxyapatite coating. The Quadra R femoral stems designs are also based on the Quadra S femoral stems in the original submission for the proximal one third with longer length for revision cases. The Quadra R femoral stems also have the application of a hydroxyapatite (HA) coating.

Indications for Use:

The Medacta Total Hip Prosthesis System is intended for cementless 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.

Comparison to Predicate Device:

The indications for use for the modified system remain the same as the original 510(k), K072857.

The Quadra H and Quadra R femoral stems are manufactured from a titanium alloy, according to ISO 5832-11, 1994, Implants for surgery – Metallic materials – part 11: Wrought titanium 6-aluminum 7-niobium alloy, the same as the Quadra S femoral stems in the original submission. They are sandblasted and the neck has a mirror polished finish, the same as the Quadra S. They have a standard 12/14 taper for connection to the ball head, the same as the Quadra S. The Quadra H and Quadra R femoral stems differ from the Quadra S in that they have a hydroxyapatite coating applied to the distal portion of the femoral stems.

The Quadra H femoral stems are available in the same four versions, standard or lateralized stem, both regular and short neck versions. The sizes, dimensions, and options are identical to the Quadra S femoral stems in the original submission.

The Quadra R femoral stems have same design and dimensions in the proximal one third as the Quadra S or Quadra H lateralized standard neck stems. The distal two thirds dimensions are longer for revision cases.

The Quadra H and Quadra R femoral stems work with the same range of ball heads cleared under the original Medacta Total Prosthesis System, K072857, and subsequent submissions for the MectaCer Ceramic ball heads, K073337, and for additional CoCrMo ball heads sizes, K080885. The Quadra H and

Quadra R 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 original devices, 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.

Risk analysis was conducted on the impact of these changes and appropriate design verification and validation was conducted under the company's design controls.

Conclusion:

The results from design controls and the information provided in this submission support the conclusion that the Medacta Total Hip Prosthesis System – Quadra H and Quadra R femoral stems are substantially equivalent to their predicate, Medacta Total Hip Prosthesis System – Quadra S femoral stems with respect to indications for use and technological characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDACTA International, SA
% NJK & Associates Inc.
Ms. Natalie J. Kennel
Consultant
1321 Via Tres Vista
San Diego, California 92129

DEC 29 2008

Re: K082792

Trade/Device Name: Medacta Total Hip Prosthesis System – Quandra J, Quandra R
Regulation Number: 21 CFR 888.3050
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: November 26, 2008
Received: December 2, 2008

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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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 K082792 (pg 1/1)

510(k) Number (if known):

Device Name: Medacta Total Hip Prosthesis System – Quadra H, Quadra R

Indications for Use:

The Medacta Total Hip Prosthesis System is intended for cementless use in total or partial hip arthroplasty and in primary or revision surgery.

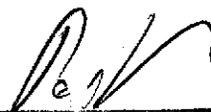
Hip replacement is indicated in the following cases:

- 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Sign Off)
**Division of General Restorative,
and Neurological Devices**

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