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JUN - 8 2012

Medacta International

510(k) Summary

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Contact Person: Mr. Adam Gross
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Date Prepared: 03/30/2012

DEVICE INFORMATION

Trade/Proprietary Name: AMIStem and Quadra - Line Extension
Common Name: Femoral Stem
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: K072857 – Medacta Total Hip Prosthesis System-
Quadra S, CoCr Ball Heads, Medacta International
K082792 - Quadra H; Quadra R, Medacta International
K093944 - AMIStem H; Quadra S-H (SN), Medacta International

Product Description

The AMIStem and Quadra - Line Extension is comprised of the following femoral stems:

- Quadra H STD #00 Short neck
- Quadra S STD #00 Short neck
- AMIStem H STD Stem #00
- AMIStem H LAT Stem #0
- AMIStem H Collared STD and LAT, multiple sizes

The subject devices have the same material as the predicate devices (titanium alloy, according to ISO 5832-11, 1994, Implants for surgery – Metallic materials – part 11: Wrought titanium 6-aluminum 7-niobium alloy).

The AMIStem H and Quadra H have the same coating as the predicate devices: Hydroxyapatite coating, material according to ASTM F1185.

The Quadra H STD #00 Short neck, Quadra S STD #00 Short neck, AMIStem H STD Stem #00, and AMIStem H LAT Stem #0 are a smaller size than the predicate devices and are intended for patients with a smaller bone structure.

The AMIStem H Collared differs from the AMIStem H (K093944) only for the presence of the collar. The collar of the stem is designed to achieve contact only with the medial femoral cortex and to provide a path for direct axial stress transfer from the prosthesis to the proximal femur avoiding the over-insertion and migration of the stem in case of subsidence.

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 Devices

The intended use, materials, and performance characteristics for all of the femoral stems that are the subject of this submission are the same as the correspondent femoral stems already registered in the predicate devices.

Performance Testing

The AMIStem and Quadra - Line Extension was tested in accordance with ISO 7206-4 and ISO 7206-6. The subject devices did not raise any new issues of safety and effectiveness and are substantially equivalent to the predicate devices.

Conclusion:
Based on the above information, the AMIStem and Quadra - Line Extension 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
% Medacta USA
Mr. Adam Gross
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4725 Calle Quetzal, Unit B
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Re: K121011
Trade/Device Name: AMIStem and Quadra – Line Extension
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: May 8, 2012
Received: May 9, 2012

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): K121011 (pg 1/1)

Device Name: AMIStem and Quadra - Line Extension

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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 K121011