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OCT 19 2012

Medacta International

510(k) Summary

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Date Prepared: September 14, 2012

DEVICE INFORMATION

Trade/Proprietary Name: Versafitcup CC Trio extension
Common Name: Acetabular Shell and Liners
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:
K103352 Versafitcup CC Trio, Medacta International
K120531 Versafitcup CC Trio - Additional Liners, Medacta International
K103721 Mpact Acetabular System, Medacta International

Product Description

The Versafitcup CC Trio family of acetabular components is designed to be used with the Medacta Total Hip Prosthesis System. The Medacta Total Hip Prosthesis system includes the Quadra S, H, R, and C Stems and CoCrMo and ceramic ball heads (K072857, K073337, K080885, K082792, K083558, and K112115). The AMIStem femoral stems also work with the Medacta Total Hip Prosthesis System (K093944, K103189). The Medacta Total Hip Prosthesis System is a total hip replacement system consisting of the femoral stem made of metal, a modular femoral head made of metal or ceramic, and acetabular components. The Versafitcup CC Trio extension that are the subject of this 510(k) consist of new sizes of flat and hooded liners, new sizes of the two-hole acetabular shell, and no-hole acetabular shells. The liners are made from either ultra-high molecular weight polyethylene (UHMWPE) or HighCross® highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE) conforming to ISO 5834. The acetabular shells are made from titanium alloy (Ti-6Al-4V) conforming to ISO 5832-3. The outside of the metal component has macrostructures in the equatorial region. The outer surface of the metallic cup has a dual layer of coatings: Ti (ASTM F 1580) plasma spray and Hydroxyapatite (ASTM F 1185).

All the Versafitcup CC Trio extension components are supplied sterile in single-use individual packages.

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, post-traumatic arthritis, rheumatoid arthritis or
psoriactic 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

The Versafitcup CC Trio extension has the same intended use, same material, and is similar in size to the liners and acetabular shells cleared in the predicate devices.

Performance Testing

The Versafitcup CC Trio extension was compared to the worst case liners and acetabular shells of the predicate devices in regards to the mechanical tests applicable to these products including range of motion, instability of connection between liner and acetabular shell, and wear. The Versafitcup CC Trio extension does not introduce any new issues in regards to safety and effectiveness.

Conclusion:
Based on the above information, the Versafitcup CC Trio 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

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Medacta International SA
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Mr. Adam Gross
Director of Regulatory and Quality
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K122911
Trade/Device Name: Versafitcup CC Trio 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: September 14, 2012
Received: September 21, 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,

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): K122911

Device Name: Versafitcup CC Trio extension

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Prescription Use ____x___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K122911