K103352

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Medacta International

FEB 11 2011

510(k) Summary

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Date Prepared: February 8, 2011

DEVICE INFORMATION

Trade/Proprietary Name: Versafitcup® CC Trio
Common Name: Total Hip Acetabular Components
Classification Name: LZO, 21 CFR 888.3353 Hip joint, metal/ ceramic/ polymer semi-constrained or nonporous uncemented prosthesis
MEH, 21 CFR 888.3353 Hip joint, metal/ ceramic/ polymer semi-constrained or nonporous uncemented prosthesis

Predicate Devices:

K993082 Exactech AcuMatch™ Integrated Hip System A-Series Porous Coated Acetabular Component
K050262 U2 Acetabular Component
K083116 Versafitcup® Double Mobility Acetabular Family, Medacta International
K092265 Versafitcup® Double Mobility HighCross® UHMWPE Liners, Medacta International
K091069 Medacta Bone Screws, Medacta International
K003758 Allofit Acetabular Cup, Zimmer

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, and K083558). The AMIStem femoral stems also work with the Medacta Total Hip Prosthesis System (K093944). 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 acetabular components that are the subject of this 510(k) consist of a metal cup made of Titanium alloy and a fixed liner that is made of ultra-high molecular weight polyethylene (UHMWPE) or HighCross® highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE).

The metal acetabular component or shell is machined 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 plasma spray and Hydroxyapatite. The polyethylene liner is a fixed liner made of UHMWPE conforming to ISO 5834. The liner has a minimum thickness of at least 5mm.

If supplemental bone screw fixation is needed, cancellous screws made of titanium alloy (Ti-6Al-4V) can be inserted through screw holes. Screw hole covers made of titanium alloy (Ti-6Al-4V) are also provided.

The metal acetabular component is available is 10 sizes which accept both CoCrMo and MectaCer BIOLOX® *forte* Ceramic ball heads with diameters of 28, 32 and 36 mm. The fixed liners are available in both flat and hooded options in a range of sizes.

All the Versafitcup® CC Trio 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 family is similar to the Exactech® AcuMatch™ Integrated Hip System A-Series Porous Coated Acetabular Components and U2 Acetabular components in indications for use, design, materials, and technological characteristics. The bone screws are similar to the Medacta Bone Screws in materials and design. The design and coating of the metal acetabular shell of the Versafitcup® CC Trio is very similar to the Versafitcup® Double Mobility acetabular shells. The HighCross® highly crosslinked UHMWPE liners of the Versafitcup® CC Trio is the same HighCross® highly crosslinked UHMWPE of which the Versafitcup® Double Mobility HighCross® UHMWPE liners are made. The design of the macrostructures on the outside of metal acetabular shells is identical to the Versafitcup® Double Mobility and similar to the Zimmer Allofit acetabular component.

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 Versafitcup® CC Trio was conducted in accordance with various international standards and FDA guidance documents.

The Versafitcup® CC Trio was tested as part of design verification to written protocols with pre-defined acceptance criteria. The testing was conducted on the worst case component size and option/design. The design verification testing included push out, lever out and rotational stability of the modular connection of the fixed liner to the metal shell, coating validation, metal shell deformation resistance during impaction, range of motion, and bone screw testing. The testing met all

acceptance criteria and verifies that the performance of the Versafitcup CC Trio is substantially equivalent to the predicate devices.

Conclusion:

The data and information provided in this submission support the conclusion that the Versafitcup® CC Trio is substantially equivalent to its main predicates devices: Exactech® AcuMatch™ Integrated Hip System A-Series Porous Coated Acetabular Component and U2 Acetabular Component with respect to indications for use and technological characteristics. The Versafitcup® CC Trio is also substantially equivalent to the Medacta Bone Screws, Versafitcup® Double Mobility Family, Versafitcup® DM HighCross® Liners and Zimmer Allofit Acetabular Cup for various technological characteristics.

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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Re: K103352
Trade/Device Name: Versafitcup CC Trio
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: November 5, 2010
Received: November 16, 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 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

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Indications for Use Statement

510(k) Number (if known):

Device Name: Medacta Versafitcup® CC Trio

Indications for Use:

The Versafitcup® CC Trio is intended for cementless use in total hip arthroplasty and 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, or 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.

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. Matkovich

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

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