K092265 IC 1/3

Medacta International

Traditional 510(k) Summary

MAR 12 2010

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@njkconsulting.com

Date Prepared: Sept. 24, 2009

DEVICE INFORMATION

Trade/Proprietary Name: Versafitcup™ Double Mobility Highcross® HXUHMWPE Liners

Common Name: Total Joint Replacement

Classification Name: Hip Joint, metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis

21 CFR 888.3353
Class II
Device Product Code: MEH

Predicate Devices:
K083116 Versafitcup™ Double Mobility System
K071718 Trilogy Longevity Constrained Liner
K061253 Reflection 3 Acetabular System
K030923 Epsilon™ Durasul® Constrained Acetabular liner

K092265 #2|3

K021911 Trident® Crossfire® Polyethylene Liners
K994415 DePuy Marathon™ Crosslinked Polyethylene Acetabular Cup Liners
K990135 Trilogy® Acetabular System Longevity® Crosslinked Polyethylene Liners

Product Description:
The Versafitcup™ Double Mobility Highcross® HXUHMWPE liners are a modification of the polyethylene liners to be made of a highly crosslinked ultra high molecular weight polyethylene. The liners are identical in sizes, dimensions and functionality as the standard UHMWPE liners which were cleared as part of the original 510(k) submission. The Highcross® UHMWPE liners are manufactured from UHMWPE that has been crosslinked by controlled exposure to radiation followed by a stabilizing heat treatment prior to machining of the liners. The crosslinked UHMWPE has physical and mechanical properties that are similar to those of standard UHMWPE but has increased resistance to wear. The Highcross® highly crosslinked UHMWPE meets all of the specifications of ASTM F648.

There is no change to the metal acetabular cup of the Versafitcup™ Double Mobility system.

The polyethylene double mobility liner is designed to articulate freely within the metal acetabular cup. The Versafitcup™ Double Mobility acetabular cup has a highly polished inner surface to facilitate this articulation.

The Versafitcup™ Double Mobility Family including the new highly crosslinked UHMWPE liners are designed to be used with the Medacta Total Hip Prosthesis' Quadra Stems and ball heads (K072857, K073337, K080885, K082792).

Indications for Use:
The Versafitcup™ Double Mobility Family 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, 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

K092265 #3/3

- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
- Dislocation risks

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™ Double Mobility Highcross® HXUHMWPE liners was conducted in accordance with various international standards and FDA guidance documents.

The Versafitcup™ Double Mobility Highcross® HXUHMWPE liners were tested as part of design verification to written protocols with pre-defined acceptance criteria. As applicable, the testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that the performance of the Versafitcup™ Double Mobility Highcross® HXUHMWPE liners are substantially equivalent to the predicate device.

Basis of Substantial Equivalence

The Versafitcup™ Double Mobility Highcross® HXUHMWPE liners have the following similarities to the standard UHMWPE liners cleared in K083116: same intended use, same raw material, same method of manufacture, same design, same sizes and dimensions, same mating components, and same sterilization and packaging methods. The new highly crosslinked liners have an increased resistance to wear as shown in simulator wear data. These in vitro results have not been correlated to clinical experience. The method of highly crosslinking of the UHMWPE is similar to that used in other cleared total hip replacement systems.

Conclusion:

The data and information provided in this submission support the conclusion that the Versafitcup™ Double Mobility Highcross® HXUHMWPE liners are substantially equivalent to its predicate device, Versafitcup™ Double Mobility family with respect to intended use, design, and operational principles. The use of highly crosslinked UHMWPE is similar to that used in other cleared total hip replacement systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Medacta International, SA
% NJK & Associates, Inc.
Ms. Natalie Kennel
13721 Via Tres Vista
San Diego, California 92129

MAR 12 2010

Re: K092265
Trade/Device Name: Versafitcup™ Double Mobility Highcross® HXUHMWPE Liners
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: MEH
Dated: February 23, 2010
Received: February 26, 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.

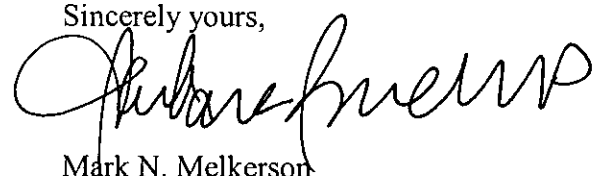
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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): K092265

Device Name: Versafitcup™ Double Mobility Highcross® HXUHMWPE Liners

Indications for Use:

The Versafitcup™ Double Mobility Family 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
- 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.
- Dislocation risks

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)

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

510(k) Number K092265