K103170 (1/3)

MAR 2 4 2011

Medacta International

510(k) Summary

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Date Prepared: March 4, 2011

DEVICE INFORMATION

Trade/Proprietary Name:	GMK® Total Knee System- Revision Semi-Constrained Liners
Common Name	Total Knee Prosthesis – Tibial Inserts
Classification Name:	Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis,
Classification:	Class II, 21 CFR 888.3560
Product Code:	JWH
Predicate Devices:	K090988 GMK® Total Knee System (Medacta International), cleared July 10, 2009

Product Description:
This modification to the original Medacta GMK® (Global Medacta Knee) Total Knee System is a line extension to include the GMK® Revision SC (Semi-constrained) liners. The GMK® Revision SC liners work with components

from the GMK® Total Knee System and from the GMK® Revision, a previously cleared Special 510(k) to the GMK® Total Knee System.

The GMK® Revision SC Liners, the subject of this 510(k), are a set of tibial inserts which work with the GMK® Revision femoral PS components and the GMK® tibial baseplates. These liners provide the surgeon with an additional option. The GMK® Revision SC Liners are offered in six sizes with seven thicknesses from 10 mm to 26 mm. The GMK® Revision SC Liners are attached to the GMK® tibial baseplates of the same size from the GMK® Total Knee System using a support peg made of CoCrMo. The device is used to replace the articular surface of the tibial plateau in the knee joint by limiting the movement of the prosthetic femoral component in translation and rotation. The GMK® Revision SC Liners attached to the GMK® tibial baseplates can also be combined with an extension stem, an offset connector and tibial wedges.

Indications for Use:
The GMK® Total Knee System is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.
This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

The tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.
In case a semi-constrined liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

Comparison to Predicate Devices
The GMK® Total Knee System was cleared under K090988. GMK® Revision components, as a line extension, was cleared under a Special 510(k), K102437. The subject of this submission is the GMK® Revision SC liners, an additional line extension of this system.

The indications for use for the modified system remain the same as the original 510(k), K090988.

The GMK® Revision SC Liners are made of Ultra High Molecular Weight Polyethylene (UHMWPE), the same material and processing, as is used in the GMK® Total Knee System's standard, ultracongruent, and posterior-stabilized (PS) tibial inserts and patellas. Like the GMK® Total Knee System's PS tibial inserts, the GMK® Revision SC liners are attached to the GMK® fixed bearing tibial baseplates, cleared in the original GMK® Total

Knee System. They are attached with a support peg, similar to the fixing screw used with the GMK® PS tibial inserts.

The GMK® Revision SC liners are offered in sizes 1 – 6, the same as all of the GMK® Total Knee System components. The GMK® Revision SC liners only work with the same size GMK® Tibial baseplate, similar to how the previously cleared tibial inserts work. The same tibial insert may be used with either a left or right hand GMK® Tibial baseplate in the same manner as the previously cleared tibial inserts. The GMK® Revision SC liners when attached to the GMK® Tibial baseplates allow the use of extension stems, offset connectors, and tibial wedges, identical to the other previously cleared tibial inserts.

The GMK® Revision SC liners differ from the tibial inserts in the GMK® Total Knee System in that they are offered in thicknesses from 10 mm to 26 mm instead of 10 mm to 20 mm. These additional thicknesses are provided as additional options to support the situations that the surgeon may encounter.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act.

The modification to the GMK® Total Knee system to include the addition of the GMK® Revision SC liners was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The testing was conducted on the worst case component size and option/design based on engineering analysis. The performance testing conducted on the GMK® Revision SC Liners was very similar to the protocols conducted for the predicate device, the GMK® Total Knee System. The testing included static and dynamic testing in the A/P direction, static testing in the M/L direction, and pullout testing of the SC liner to the tibial baseplate. Rotary/laxity and varus/valgus testing was also conducted. Range of motion and contact area were both evaluated in comparison to the predicate device. The testing met all acceptance criteria and verifies that performance of the GMK® Revision SC Liners are substantially equivalent to the predicate device system, GMK® Total Knee System.

Conclusion:

The results from design controls and the information provided in this submission support the conclusion that the GMK® Total Knee System-Revision SC Liners is substantially equivalent to its predicate device with respect to indications for use and technological characteristics.

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

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MAR 24 2011

Re: K103170
Trade/Device Name: GMK® Total Knee System – Revision SC Liners
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: March 4, 2011
Received: March 7, 2011

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): K103170

Device Name: GMK® Total Knee System – Revision SC Liners

Indications for Use:
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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. Mellerson

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

510(k) Number K103170