JUL 10 2009

Medacta International

510(k) Summary

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Date Prepared: March 31, 2009

DEVICE INFORMATION

Trade/Proprietary Name: GMK® - Total Knee System
Common Name Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis, 21 CFR 888.3560

Predicate Devices:

K081023 Evolis Total Knee System (Medacta International)
K072858 TC Plus Primary Knee System (Smith and Nephew)
K043101 NexGen® Complete Knee Solution MIS Tibial Components (Zimmer)
K021657 UKNEE Total Knee System (United Orthopedic Corporation)

Product Description:
The GMK® Total Knee System is a tricompartmental fixed bearing total knee prosthesis comprised of femoral, patellar, and tibial components with ultra-high molecular weight polyethylene articular inserts. The femoral components are offered in left and right sizes in a standard and a posterior

stabilized design of six sizes. The tibial baseplates are offered in six left and right sizes with an optional extension stem of 65 mm length. The tibial inserts are offered in three styles: standard, posterior-stabilized and ultra-congruent. Each of the three styles is offered in six sizes, corresponding to the tibial base plate sizes, in five thicknesses from 10 - 20 mm each. Tibial inserts work with either the left or right tibial baseplate of that size. The patellar components are offered in two options: an inset patella and a resurfacing patella. The inset patella is offered in the three diameters of 24, 28, and 32 mm and the resurfacing patella is offered in three sizes.

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.

Comparison to Predicate Devices
The GMK® Total Knee System has the same indications for use as the main predicate device, the Evolis Total Knee System. The GMK® Total Knee System components are made of the same type of materials for each component as one or more of the predicate devices. The GMK® Total Knee System components' design and technological characteristics are similar to one or more of the predicate devices. The GMK® Total Knee System components are packaged and sterilized in the manner as the main predicate, the Evolis Total Knee System.

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 GMK® Total Knee System was conducted in accordance with various international standards and FDA guidance documents.

The GMK® Total Knee System was tested as part of design verification to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the above standards and guidance. The testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that performance of the GMK® Total Knee System is substantially equivalent to the predicate devices.

Conclusion:
The data and information provided in this submission support the conclusion that the GMK® Total Knee System is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medacta International, SA
c/o Ms. Natalie J. Kennel
Consultant, NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

JUL 10 2009

Re: K090988
Trade/Device Name: GMK® Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint, Patellofemorotibial, metal/polymer/metal, semiconstrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 15, 2009
Received: June 17, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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 (240) 276-3150 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

K090988

Indications for Use Statement

510(k) Number (if known): K090988

Device Name: GMK® Total Knee System

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

510(k) Number K090988