K071881

OCT - 9 2007

510(k) Summary of Safety and Effectiveness
Triathlon® Knee System Line Extension

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Vivian Kelly, Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	July 6, 2007

Device Identification

Proprietary Name:	Triathlon® PKR System
Common Name:	Knee Prosthesis Components
Classification Name and Reference:	Knee Joint, Femorotibial, Polymer/Metal, Semi-constrained, Cemented Prosthesis, 21 CFR §888.3530
Proposed Regulatory Class:	Class II
Device Panel/Product Code:	87 HRY, Prosthesis, Knee, Femorotibial, semi-constrained, Cemented, Metal/Polymer

Description:

The Triathlon® PKR System is a modular unicondylar knee prostheses consisting of sterile, single-use components intended for replacement of the medial or lateral femoral condyle regions for either the right or left knee.

Indications for Use:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are intended for implantation with bone cement.

Substantial Equivalence:

The device is substantially equivalent to its predicates for femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The analyses demonstrate that the components from these systems are compatible when used for femorotibial replacement. Examples of predicate knee systems include the Triathlon® Knee System (K031729, K040267) and X3® UHMWPE Tibial Inserts and Patellar Components (K051146 & K063423), the EIUS® Unicompartmental Knee System (K992287 & K033769), the SCR® Unicompartmental Knee Prosthesis (K896856 & K911373) and the UNIX™ Unicompartmental Knee System (K923011.) Based upon the mechanical testing, the Triathlon® PKR System is substantially equivalent for its intended use to other femorotibial replacement knees currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2007

Howmedica Osteonics Corp.
% Ms. Vivian Kelly, RAC
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430

Re: K071881
Trade/Device Name: Triathlon PKR System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: July 6, 2007
Received: July 9, 2007

Dear Ms. Kelly:

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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071881

Device Name: Triathlon® PKR System

Indications for Use:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 General, Restorative, and Neurological Devices

510(k) Number K071881