K123166

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510(k) Summary

FEB 14 2013

Sponsor	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Audrey Witko Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: 201-831-6717/Fax: 201-831-3717
Date Prepared:	October 8, 2012, revised February 11, 2013
Proprietary Name:	Triathlon® All-Polyethylene Condylar Stabilizing (CS) and Posterior Stabilizing (PS) Tibial Implants
Common Name:	Total Knee Replacement
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – 888.3560
Product Code:	JWH - Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Triathlon® Condylar Stabilizing (CS) Lipped Insert: K063423
Triathlon® Posterior Stabilized (PS) Total Knee System: K050539, K042993 and K031729
Scorpio® Posterior Cruciate Retaining (CR) Total Knee System All-Poly Tibia: K974556
Scorpio® Posteriorly Stabilized (PS) Total Knee System All Poly Tibia: K962152
Triathlon® TS Knee System: K072221

Device Description: The subject devices are a line extension to the Triathlon® Total Knee System (K063423, K050539, K042993 and K031729), providing an all-polyethylene tibial component in CS and PS designs. The All-Poly CS and PS Tibial implants are similar in intended use, design, materials, mechanical testing and operational priniciples as the predicate devices. These components are designed for cemented use only.

There have been no prior submissions for these devices.

These implants are compatible for use with the Triathlon® PS, TS and CR Femoral Components (cemented and uncemented), Triathlon® PS and CR Femoral Components with PA (uncemented), Triathlon® Symmetrical Patellar Component [Conventional or X3® UHMWPE] (cemented), Triathlon® Asymmetrical Patellar Component [Conventional or X3® UHMWPE]

(cemented), Triathlon® Metal-Backed Patellar Component with PA (uncemented), Duracon® Symmetric Patellar Component (cemented), Duracon® Asymmetric Patellar Component (cemented), and Duracon® Inset Patellar Component (cemented).
Intended Use: The Triathlon Triathlon® All-Polyethylene Condylar Stabilizing (CS) and Posterior Stabilizing (PS) Tibial Implants are for cemented use in primary and revision Total Knee Arthroplasty.

Indications:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Additional General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:
- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

The Triathlon All Polyethylene tibial components are indicated for cemented use only.

Summary of Technologies: The Triathlon All-Poly Tibial Implant is designed to be substantially equivalent to the Scorpio All-Poly Tibial Implant and the Triathlon polyethylene inserts. The Triathlon All-Poly Tibial Implant articular surface and periphery is designed equivalently to the existing Triathlon inserts. The bottom side of the All-Poly Tibial Implant is designed with the Scorpio All-Poly Tibial Implant cement features to which was added a line to line boss with flat posterior section that ensures the cement mantle is even around the keel (the Scorpio design allows the keel to be shifted and have varying cement thicknesses).

Non-Clinical Testing: Deflection and Micromotion testing were performed to verify design and establish the basis for substantial equivalence. Micromotion testing was conducted to show the difference in force/motion that the cement and bone interface would see in response to the change of articulation and periphery when utilizing the Scorpio cement features. The deflection test was conducted to make sure that the stiffness (and strength) of the Triathlon All-Poly Tibial Implant component was equivalent or better then the Scorpio All-Poly Tibial Implant with change to the articulation and periphery. Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Triathlon® All-Polyethylene Condylar Stabilizing (CS) and Posterior Stabilizing (PS) Tibial Implants are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 14, 2013

Howmedica Osteonics Corporation
% Ms. Audrey Witko
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K123166
Trade/Device Name: Triathlon® All-Polyethylene Condylar Stabilizing (CS) and Posterior Stabilizing (PS) Tibia Implants
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: January 8, 2013
Received: January 15, 2013

Dear Ms. Witko:

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,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123166

Device Name: Triathlon® All-Polyethylene Condylar Stabilizing (CS) & Posterior Stabilizing (PS) Tibia Implants

Indications for Use:

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The Triathlon All Polyethylene tibial components are indicated for cemented use only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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