JAN 12 2005

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 325 Commerce Court Mahwah, NJ 07430
For Information contact:	Denise Duchene Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Commerce Court Mahwah, NJ 07430

Device Identification

Proprietary Name:	Triathlon™ Posteriorly Stabilized (PS) Femoral Component (5515)
Common Name:	Posteriorly Stabilized Knee Femoral Component
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

It is the intention of Howmedica Osteonics Corp. to modify the design of the Triathlon™ Posteriorly Stabilized (PS) Femoral Component (previously released under K031729) to improve component manufacturability.

The design change for the Triathlon™ PS Femoral Component involves a removal of material from the superior, posterior region of the cam (or box) section of the femoral

component adjacent to the posterior femoral condyles. This material is being removed to improve manufacturability of the component. The articular surface designs of the component (both patello-femoral and tibio-femoral) are unchanged by this modification.

The intended use of the Triathlon™ PS Femoral Component is identical to that of the predicate: it is intended to be used with Triathlon™ PS tibial inserts, Triathlon™ Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid 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 Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.

- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The modified Triathlon™ PS Femoral Component (catalog number 5515) is identical to the previously released Triathlon™ PS Femoral Component in terms of intended use, material, and general design features. The only difference is the removal of material from the superior, posterior portion of the cam. Physical testing was performed to show that the component could withstand load over ten million cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Denise Duchene
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Commerce Court
Mahwah, New Jersey 07430

Re: K042993
Trade/Device Name: Triathlon™ Posteriorly Stabilized PS Femoral Component (5515)
Regulation Name: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/ metal/ polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: October 29, 2004
Received: November 1, 2004

Dear Ms. Duchene:

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 Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042993 42

510(k) Premarket Notification– Triathlon™ PS Femoral Component (5515)

510(k) Number (if known): K

Device: Triathlon™ Posteriorly Stabilized (PS) Femoral Component (5515)

The Triathlon™ PS Femoral Component has undergone a design modification – material has been removed from the superior, posterior aspect of the cam. This design change has been made to improve the manufacturability of the component. The intended use of the Triathlon™ PS Femoral Component is: it is intended to be used with Triathlon™ PS tibial inserts, Triathlon™ Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. Specific indications:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid arthritis
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Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament

for Mark A. Millerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042993

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042993