K070095
510(k) Summary of Safety and Effectiveness for the
Triathlon® TS Knee System

JUN - 1 2007

Proprietary Name:	Triathlon® TS Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3560
Regulatory Class:	Class II
Device Product Code:	87 JWH - prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5412 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	June 1, 2007

Device Description

A total stabilizing version of the Triathlon Total Knee System has been developed and will now include femoral components and tibial inserts compatible with the Triathlon universal tibial components cleared previously. The new Triathlon TS Knee is designed to accommodate patients with severely deficient bone stock who require additional components for increased stabilization. The Triathlon TS System will include femoral components, stem extenders, offset adapters, stems, and tibial inserts in standard and TS Plus design. Implants will be available in sizes 1 through 8. Product descriptions, product codes and engineering drawings are provided for review.

Intended Use:

The Triathlon TS Total Knee System components are intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. All total knee components presented in this submission are provided sterile for single-use.

Indications for Use

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory 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 Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

The Triathlon TS Total Knee System components are intended for cemented use only.

Substantial Equivalence:

The determination of the substantial equivalence of the Triathlon TS total knee system is based on similarities in intended use, design and sterilization to the Howmedica Total Stabilizing Total Knee System (K973164, cleared August 22, 1997), Triathlon PS Knee System (K031729, cleared September 2, 2003 and K042993 cleared January 12, 2005) and the Triathlon® Total Knee System (K053514, cleared January 26, 2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2007

Howmedica Osteonics Corp.
c/o Ms. Tiffani D. Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K070095
Trade/Device Name: Triathlon TS Knee System
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: May 17, 2007
Received: May 18, 2007

Dear Ms. Rogers:

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.

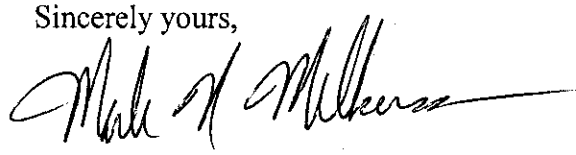
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 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

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

510(k) Number: K070095

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The Triathlon TS Total Knee System components are intended for cemented use only.

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)