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JUL 13 2005

510(k) Summary of Safety and Effectiveness

Device: Triathlon® X3™ UHMWPE Tibial Inserts and Patellar Components

Classification: 21 CFR 888.3560 – Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis

Product Code 87 JWH,

Predicate Devices: Triathlon® Tibial Inserts and Patellar

Contact Person: Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
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Date Summary Prepared: May 3, 2005

The Triathlon® X3™ UHMWPE Posterior Stabilized and Cruciate Retaining tibial inserts and the Triathlon® X3™ UHMWPE Patellar components are intended to be used with the cemented Triathlon® PS and CR femoral components and cemented Triathlon® Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon® X3™ UHMWPE Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System The Triathlon® PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. The Triathlon® CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The all polyethylene Triathlon® X3™ UHMWPE Patellar components are intended for implantation with bone cement only.

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 device includes tibial and patellar components of a total knee system. These components are used for the replacement of the bearing and/or articulating surfaces of the proximal tibia and patella. Tibial inserts will be made in Cruciate Retaining and Posterior Stabilized designs. Patellar components will be made in both Asymmetric and Symmetric designs.

Summary of Data

A risk analysis and research and development testing have been performed to demonstrate equivalence of the subject products to the predicate devices. Testing and analysis includes material properties testing, wear testing, disassembly force evaluation, multi-axis fatigue testing, patella shear testing and finite element modeling of contact stresses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051146
Trade/Device Name: Triathlon® X3™ UHMWPE Tibial Inserts and Patellar Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: May 3, 2005
Received: May 4, 2005

Dear Ms. Ariemma:

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 north 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,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051146 (pg. 1 of 2)

510(k) Number (if known): _____

Device Name: Triathlon® Knee System

Indications for Use:

The Triathlon® X3™ UHMWPE Posterior Stabilized and Cruciate Retaining tibial inserts and the Triathlon® X3™ UHMWPE Patellar components are intended to be used with the cemented Triathlon® PS and CR femoral components and cemented Triathlon® Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon® X3™ UHMWPE Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System The Triathlon® PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. The Triathlon® CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The all polyethylene Triathlon® X3™ UHMWPE Patellar components are intended for implantation with bone cement only.

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- 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.
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- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.

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Division of General, Restorative and Neurological Devices

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- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
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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)

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

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