MAY 3 2013

510(k) Summary

Sponsor	Homedica Osteonics Corp. 325 Corporate Drives Mahwah, NJ 07430
Contact Person	Audrey Witko Sr. Regulatory Affairs Specialist 1-201-831-6717
Date Prepared:	November 9, 2012
Proprietary Name:	Triathlon® Tritanium Tibial Baseplates
Common Name:	Total Knee Joint Replacement
Classification Name:	Knee joint Patellofemorotibial metal/polymer porous-coated Uncemented prosthesis. (888.3565, 87MBH) Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560, 87JWH)

Legally Marketed Device to Which Substantial Equivalence is Claimed:
- Howmedica Osteonics Corp. - Triathlon® Total Knee System – K051380
- Zimmer, Inc. – NexGen® Trabecular Metal™ Tibial Tray – K072160

Device Description: The Triathlon® Tritanium Tibial Baseplate is an extension of the Triathlon® Total Knee System product line for use in primary or revision Total Knee Arthroplasty. It is a sterile, single patient use, tibial baseplate and will be offered in the same size range as the current Triathlon® cementless baseplates (Sizes 1-8). This porous-coated baseplate is for use in both cemented and cementless applications. The Triathlon® Tritanium Tibial Baseplates are packaged with a sterile, single patient use, disposable Impactor Pad in-situ. The Impaction Pad is to be used during the tibial baseplate impaction step only, and is to be discarded once the impaction has been completed. The Impaction Pad is not for implantation.

The Triathlon® Tritanium Tibial Baseplate is compatible for use with the Triathlon® PS, CS and CR Tibial Inserts (N_2Vac or X3 polyethylene), Triathlon® PS and CR Femoral components (cemented & cementless), Triathlon® Symmetric Patellar components (N_2Vac or X3 polyethylene) (cemented), Triathlon® Asymmetric Patellar components (N_2Vac or X3 polyethylene) (cemented), Triathlon® Metal Backed Asymmetric Patellar with PA (cementless), Duracon® Symmetric & Asymmetric Patellar components (cemented), and Duracon® Inset Patella component (cemented) . These implants may also be used with ShapeMatch® Cutting Guides.

Intended Use: The Triathlon® Tritanium Tibial Baseplates are designed to be implanted with or without bone cement in primary or revision Total Knee Arthroplasty procedures.

Indications:

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) Components:

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

The Triathlon® Tritanium Tibial Baseplates are indicated for Cemented or Cementless use.

Summary of Technologies: Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

Non-Clinical Testing: The following non-clinical laboratory testing was performed to determine substantial equivalence: mechanical properties of the materials (ASTM F1580, ASTM F67, ASTM F136, ASTM F1147, ASTM F1044, ASTM F1160), device fatigue strength (ASTM F1800, ASTM F2083), and wear evaluation of conventional polyethylene inserts comparing subject and predicate devices (ASTM F2025, ISO 14243-3). In addition to the preceding Standards, the FDA Guidance Document entitled 'Guidance document for testing orthopaedic implants with modified metallic surfaces apposing bone or bone cement,' dated April 28, 1994, has been followed.

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

Conclusion: The Triathlon® Tritanium Tibial Baseplate is 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 20993-0002

May 3, 2013

Homedica Osteonics Corporation
% Ms. Audrey Witko
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K123486
Trade/Device Name: Triathlon® Tritanium® Tibial Baseplates
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: April 26, 2013
Received: April 29, 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 contact 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. 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 D. 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): K123486

Device Name: Triathlon® Tritanium® Tibial Baseplates

Indications for Use:

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The Triathlon® Tritanium® Tibial Baseplates are indicated for both cemented and uncemented use.

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices