**Exactech® Tapered Wedge Femoral Stem**
**Traditional 510(k)**

JUN 3 0 2014

**510(k) Summary**

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| **Company:** | Exactech®, Inc<br>2320 NW 66th Court<br>Gainesville, FL 32653 |
| **Date:** | June 30, 2014 |
| **Contact Person:** | Shing Jen Tai, PhD<br>Sr. Regulatory Affairs Specialist<br><br>Phone: (352) 327-4638<br>Fax: (352) 378-2617 |
| **Proprietary Name:** | Exactech® Tapered Wedge Femoral Stem |
| **Common Name:** | Femoral Hip Stem |
| **Classification Names for Proposed Device:** | 21 CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis;<br>21 CFR 888.3390, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis; |
| **Classification Names for Compatible Devices:** | 21 CFR 888.3350, Hip joint metal/polymer semi-constrained cemented prosthesis<br>21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis<br>21 CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis<br>21 CFR 888.3310, Hip joint metal/polymer constrained cemented or uncemented prosthesis<br><br>Class II |
| **Product Codes for Proposed Device:** | LZO, MEH, KWY |
| **Product Codes for Compatible Devices:** | JDI, LPH, LWJ, KWZ |

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**Legally Marketed Device to Which Substantial Equivalence Is Claimed:**

- Accolade II Hip Stem (K120578) from Howmedica Osteonics Corp. (a subsidiary of Stryker Corporation)
- Taperloc Complete (K101086, and K103755 - line extension to devices cleared in K101086) from Biomet Inc.
- Novation 12/14 Press-Fit Femoral Stems (K042842) from Exactech Inc.

**Device Description**

Exactech Tapered Wedge Femoral Stem is a collarless, press-fit prosthesis featuring a 12/14 trunnion that is used on the femur side of a total or hemi hip arthroplasty. The overall design goal of the Exactech Tapered Wedge Femoral Stem is to emphasize medial/lateral fixation of the device and axial/rotational stability when implanted in the femoral/medullary canal.

Manufactured from titanium alloy, the subject stem is available in 17 sizes with two lateral offsets offered for each size and two surface finish options (commercially pure titanium, and hydroxylapatite over commercially pure titanium) for the press-fit region of the device. Together, there are 68 total femoral stem configurations available to accommodate patients' various anatomical needs. Regardless of configuration, all Tapered Wedge Femoral Stems feature a polished neck region and bead blast (satin) surface finish on the distal region of the femoral stem. Exactech Tapered Wedge Femoral Stems are intended for press-fit applications. With respect to device-compatibility with other Exactech manufactured products, Tapered Wedge Femoral Stem is designed to be used with the following 12/14 femoral heads and AcuMatch bipolar components.

The proposed femoral stems are intended to mate with the following modular 12/14 femoral heads:

- Exactech Cobalt Chromium Alloy Femoral Heads (K041906, K121392)
- Exactech Ziramic Zirconia Femoral Heads (K050398, K060107)
- Exactech BIOLOX®forte Alumina Femoral Heads (K032964, K051682)
- Exactech *Biolox*Delta and *Biolox*Option Femoral Heads and Adapters (K103012, K121392)
- Exactech AcuMatch L-series Unipolar endoprosthesis (K010081)

The proposed femoral stems are intended to mate with the following bipolar components:

- Exactech AcuMatch L-Series Bipolar Endoprosthesis (K013211)

The Exactech Tapered Wedge Femoral Stem is accompanied by a complete instrumentation set including trial and broach/rasp system to assist surgeons in implantation of the device.

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**Indications for Use**
All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

**Summary of Technological Characteristics**
The rationale for substantial equivalence is based on consideration of the following device use and characteristics:

- **Indications for Use.** The proposed Exactech Tapered Wedge Femoral Stem and the predicate devices have same or similar indications for use.
- **Materials/Surface Finish/Coatings.** The proposed Exactech Tapered Wedge Femoral Stem and the predicate devices are composed of similar, biocompatible substrate materials, and the same or similar surface finish/coatings for permanent implants.
- **Design Features.** The proposed Exactech Tapered Wedge Femoral Stem and the predicate devices share similar design features.
- **Dimensions.** The proposed Exactech Tapered Wedge Femoral Stem and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Exactech Tapered Wedge Femoral Stem and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech Tapered Wedge Femoral Stem and the predicate devices conform to recognized performance standards for total hip replacement devices.

**Non-Clinical Testing**
The following clinical literature review, template studies, mechanical testing, and cadaveric evaluation were performed to demonstrate that the Exactech Tapered Wedge Femoral Stem performs as intended and is substantially equivalent to the identified predicate devices:

- Clinical Literature Review of similar femoral prostheses.
- Template Studies.
- Range of Motion Testing per ISO 21535.

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- Distally Fixed Fatigue Testing of worst case per FDA guidance.
- Femoral Neck Fatigue Testing of worst case per FDA guidance.
- Femoral Head Modular Junction Burst Testing, Fatigue Testing, and Axial pull-off Testing on Exactech taper specification per ISO 7206-10 and ASTM F2009-00.
- Cadaveric evaluation.
- Microstructural characterization and mechanical testing completed for the dual coating of the Exactech Tapered Wedge Femoral Stem.
- Biocompatibility testing performed on the colorants used in production of instruments.

**Substantial Equivalence Conclusion**

Based on consideration of indications for use, technological characteristics, and results of combined mechanical testing, cadaveric validation study, template studies, and clinical literature review described above, it was concluded that Exactech Tapered Wedge Femoral Stem demonstrates substantial equivalence to the referenced predicate devices.

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

June 30, 2014

Exactech Inc.
Dr. Shing Jen Tai
Senior Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K140674
Trade/Device Name: Exactech® Tapered Wedge Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, KWY, LPH, JDI, LWJ, KWZ
Dated: May 23, 2014
Received: May 27, 2014

Dear Dr. Tai:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

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**Indications for Use Statement**

**510(k) Number:** K140674

**Device Name:** Exactech® Tapered Wedge Femoral Stem

**INDICATIONS FOR USE:**
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**Prescription Use** X **and/or** **Over-The-Counter Use** _____
**(Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Elizabeth L. Frank -S

Division of Orthopedic Devices