K103012 #1/3

BIOLOX®*Delta* and BIOLOX® Option Femoral Heads
Special 510(k) – 510(k) Summary of Safety and Effectiveness

NOV 10 2010

I. **Company:**

Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

Contact Person: Lindy Knisely

Date: November 10, 2010

II. **Proprietary Name:**
Exactech BIOLOX®Delta Femoral Heads and BIOLOX® Option Femoral Heads and Adapters

Common Name: Femoral Head

Classification Name:

- Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented

III. **Legally Marketed Devices to Which Substantial Equivalence Is Claimed:**

510(k) Number	Trade of Proprietary Model Name	Manufacturer
K032964	Exactech 12/14 Alumina Femoral Heads	Exactech, Inc
K051682	Exactech 12/14 Alumina Femoral Heads 36mm	Exactech, Inc

IV. **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. Press-fit components without hydroxyapatite (HA) coating may also be used with bone cement at the discretion of the surgeon.

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- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

V. Device Description

The proposed Exactech BIOLOXdelta femoral heads and Biolox Option femoral heads and adapters are modifications to the existing Exactech 12/14 Alumina heads previously cleared in K032964 and K051682. The proposed femoral heads and adapters have the same general design features as the predicate device. The proposed femoral heads are manufactured from an alumina/zirconia based ceramic material known as Delta per ISO 6474-2. The Biolox Option adapters are comprised of titanium alloy per ISO 5832-3 and are intended for use with the Biolox Option femoral heads for primary and revision applications in which the taper remains intact.

The proposed femoral heads mate with the following devices:

- 12/14 Femoral Stems
  - Novation Press-Fit Femoral Stems (K042842)
  - Novation Splined RDD Femoral Stem (K063279)
  - Novation Element Press-Fit Femoral Stem (K080980)
  - Novation Cemented Stems (K052787)
  - Novation Cemented Plus (K083392)
  - AcuMatch Press Fit Stems (K041906, K051335)
  - AcuMatch Cemented Stems (K052787)
  - AcuMatch M-Series (K032964, K051858)
- Acetabular Liners
  - Novation Crown Cup Standard and GXL UHMWPE Liners (K070479, K100269)
  - Novation Crown Cup Constrained Liners (K071676)
  - AcuMatch A-Series Standard and GXL UHMWPE Liners (K993082, K000242, K040613, K051556)
  - AcuMatch Constrained Liners (K040601)

The predicate and proposed devices have the same intended use and basic fundamental scientific technology and share the following similarities:

- similar indications for use
- similar design features
- incorporate similar materials
- the same shelf life
- are packaged and sterilized using the same materials and processes

VI. Summary of Non-Clinical Performance Data

The following engineering evaluations were conducted to demonstrate substantial equivalence of the proposed devices to the predicate devices:

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- Burst strength (ISO-7206-10)
- Fatigue strength (ISO-7206-10)
- Post fatigue strength(ISO-7206-10)
- Pull off force and Torque (Ceramtec specifications and FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems)

VII. Substantial Equivalence Conclusion:

Device Comparison	Predicate	Proposed
Femoral Head	12/14 Alumina Femoral Heads	Biolox*delta* Femoral Heads Biolox Option Femoral Heads and Adapters
Manufacturer	Exactech, Inc	
Intended Use	Primary Hip Arthroplasty	Biolox*delta*: Primary Hip Athroplasty Biolox Option: Primary or Revision Hip Arthroplasty
Indications for Use	Similar indications for use	
Stem Compatibility	12/14 Ti-6Al-4V or CoCr Tapers with geometry to accept ceramic head	
Material Composition	Conforms to recognized industry standards and requirements	
Taper Bore Geometry	Similar geometry to be compatible with 12/14 trunnions	
Head OD Sizes	Same OD size range	
Head Offset Sizes	-3.5mm, +0mm, +3.5mm	-3.5mm, +0mm, +3.5mm, +7mm
Sterile Barrier Packaging	Same packaging materials	
Sterilization	Same sterilization method	

Results of engineering analyses referenced in this 510(k) submission demonstrate that the proposed Biolox*delta* femoral heads and Biolox Option femoral heads and adapters are substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Ms. Lindy Knisely, R.N.
Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

NOV 10 2010

Re: K103012
Trade/Device Name: BIOLOX® Delta Femoral Heads and BIOLOX® Option Femoral Heads and Adapters
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
Dated: October 8, 2010
Received: October 12, 2010

Dear Ms. Knisely:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

BIOLOX® *Delta* and BIOLOX® Option Femoral Heads
Special 510(k) – Indications for Use

510(k) Number: K103012

NOV 10 2010

Device Name: BIOLOX® *Delta* Femoral Heads and BIOLOX® Option Femoral Heads and Adapters

Indications:

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.

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- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103012