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Exactech® Femoral Heads and Novation® Crown Cup® Acetabular Liners
Special 510(k) – 510(k) Summary of Safety and Effectiveness

JAN 16 2013

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

Phone: (352) 377-1140
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FDA Establishment Number 1038671

Contact: Nicole Kassner
QA/RA Compliance, Project Manager

Date: January 11, 2013

Trade of Proprietary or Model Name(s):
Exactech® Novation® Crown Cup® GXL UHMWPE Liner
Exactech 12/14 CoCr Femoral Head
Exactech 12/14 Biolox*delta*® Femoral Head
Exactech 12/14 Biolox Option Femoral Head
Exactech Novation Crown Cup 40mm Liner Trials
Exactech 12/14 40mm Head Trials

Common Name:
Total Hip Arthroplasty Prosthesis – Acetabular Liners and Femoral Heads

Classification Name:
Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Class II, Product Code LZO)

Prosthesis, hip, semi-constrained, metal/polymer, cemented (CFR 888.3350, Hip joint metal/polymer semi-constrained cemented, Class II, Product Code JDI)

Prosthesis, hip, semi-constrained, metal/polymer, uncemented (CFR 888.3360, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, Class II, Product Code LWJ)

Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate (CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Class II, Product Code MEH)

Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Class II, Product Code LPH)

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Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade of Proprietary Model Name	Manufacturer
K070479	Exactech Novation® Crown Cup® Liners	Exactech, Inc.
K041906	Exactech 12/14 CoCr Femoral Heads	Exactech, Inc.
K103012	Exactech Biolox*delta*® and Biolox Option Femoral Heads and Adapters	Exactech, Inc.

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.

Device Description:
The proposed Novation Crown Cup Acetabular Liners and associated Liner Trials are a modification to the Novation Crown Cup Acetabular Liners and associated Liner Trials cleared through premarket notification #K070479.

The proposed 12/14 Cobalt Chromium, Biolox*delta* and Biolox Option Femoral Heads and associated Head Trials are a modification to the 12/14 Cobalt Chromium, Biolox*delta* and Biolox Option Femoral Heads and associated Head Trials cleared through premarket notifications #K041906 and #K103012.

The predicate and proposed devices have the same intended use and basic fundamental scientific technology.

The modified devices share the following similarities with the predicate devices:
- Indications for use
- Design features
- Material
- Shelf life

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- Packaging and sterilization materials and processes

This submission proposes the following design change:

- The proposed acetabular liners have a minimum polyethylene thickness of 4mm for compatibility with 32mm, 36mm and 40mm femoral heads.
- The proposed femoral heads have an outer diameter of 40mm.

Substantial Equivalence Conclusion:
The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed devices to the predicate devices:

- Wear testing per ASTM F1714 to determine that the proposed devices have equivalent or better wear results than the predicate devices.
- Lever-out testing per Tradonsky, et al. 1993, Axial push-out per ASTM F1820, Torque testing was conducted to determine that the proposed acetabular liner devices are substantially equivalent to the predicate devices.
- Impingement fatigue testing was conducted to determine that the proposed acetabular liner devices are substantially equivalent to the predicate devices.
- Engineering justification to support the applicability of the predicate device testing to the proposed devices:
    - Burst Testing per ISO 7206-10
    - Fatigue per ISO 7206-10
    - Post Fatigue per ISO 7206-10
    - Pull-Off per Ceramtec specifications, FDA Guidance and ASTM F2009
    - Torque per Ceramtec specifications, FDA Guidance
    - Range of Motion per ISO 21535

The results of engineering analyses demonstrate the proposed devices are substantially equivalent to the 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

January 16, 2013

Exactech, Incorporated
% Ms. Nicole Kassner
Quality and Regulatory Compliance Project Manager
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K121392
Trade/Device Name: Exactech® Femoral Heads and Novation® Crown Cup® Acetabular Liners
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, JDI, LWJ, MEH, LPH
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Kassner:

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,

Erin D. Keith

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

Enclosure

Exactech® Femoral Heads and Novation® Crown Cup® Acetabular Liners
Special 510(k) – Indications for Use

510(k) Number: _____

Device Name: Exactech® Femoral Heads and Novation® Crown Cup® Acetabular Liners

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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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 – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi, PhD
Division of Orthopedic Devices