K100269

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

I. **Company:**

Exactech, Inc.
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Gainesville, FL 32653

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MAY 27 2010

**Contact Person:** Graham L. Cuthbert, Regulatory Affairs Specialist II

**Date:** January 22, 2010

II. **Proprietary Name:** Exactech® Novation® Crown Cup® and Liners

**Common Name:** Acetabular Components

**Classification Name:**

- Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (21 CFR 888.3358, Class II, Product Code LPH)
- Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (21 CFR 888.3353, Class II, Product Code LZO)
- Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate (21 CFR 888.3353, Class II, Product Code MEH)
- Prosthesis, hip, semi-constrained, metal/polymer, uncemented (21 CFR 888.3360, Class II, Product Code LWJ)
- Prosthesis, hip, semi-constrained, metal/polymer, cemented(21 CFR 888.3350, Class II, Product Code JDI)

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

| 510(k) Number | Trade of Proprietary Model Name | Manufacturer |
|---|---|---|
| K070479 | Novation® Crown Cup® and Liners | Exactech, Inc |

IV. **Device Description:**

Total Hip Arthroplasty (THA) is the replacement of the acetabular and femoral portions of the hip joint. The acetabular aspect of THA includes the replacement of a portion of the pelvis called the acetabulum with a prosthetic cup or an assembly of a modular shell and liner.

The proposed no-hole and cluster hole modular Crown Cups are manufactured from titanium alloy (Ti-6Al-4V) and are available with commercially pure (CP) titanium plasma-spray coating or CP titanium plasma-spray with hydroxylapatite coating applied to the exterior. The CP titanium plasma spray provides initial mechanical fixation and bony on growth. The holes allow for the use of 6.5 mm screws that will enhance the primary fixation, if needed.

The proposed Crown Cup liners are available in cross-linked Connection GXL Ultra High Molecular Weight Polyethylene (UHMWPE) (ASTM F648) and come in neutral, lipped, lateralized +5mm, and 10 degree face-changing lateralized +5mm configurations.

The proposed cups mate with the following devices:

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- Novation Crown Cup GXL Liners (proposed –subject of this review)
- Novation Crown Cup GXL and Std, Group 3 Liner (K070479)
- Exactech Bone Screws (K993082)

The proposed liners mate with the following devices:

- Novation Crown Cup acetabular shells (proposed –subject of this review)
- Exactech CoCr Femoral Heads (#K041906, #K862334)
- Exactech Zirconia Femoral Heads (#K050398, #K060107)
- Exactech BioloxForte Alumina Femoral Heads (#K032964, #K051682)

## V. Intended Use of the Device

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

## VI. Rationale for Substantial Equivalence

- **Intended Use.** The proposed Novation Crown Cups and Liners and predicate devices are intended for use in total hip joint replacement and have identical indications for use statements.
- **Materials.** The proposed Novation Crown Cups and Liners and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants. The hydroxylapatite coating is the same as described in 510(k) #K070479.
- **Sterilization processes.** The proposed Novation Crown Cups and Liners and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Design Features.** The proposed Novation Crown Cups and Liners and predicate devices incorporate similar design features including the apical lock mechanism.
- **Performance specifications.** The proposed Novation Crown Cups and Liners and predicate devices conform to recognized performance standards for total hip replacement devices.

The proposed modifications for the cups include an addition to product scope, hemispherical overall height, elimination of the constrained liner feature and a modified cup thickness. The modifications for the liners include addition in scope of the product, hemispherical overall height, modified inner diameter (ID) chamfer, and a modified liner thickness.

## VII. Summary of Non-Clinical Performance Data

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Mechanical tests and engineering analyses were conducted to support the claim of substantial equivalence to the predicate Novation Crown Cups and Liners. A summary of these tests and analyses are as follows:

- A design rationale and dimensional analyses compared to the predicate devices demonstrating the substantial equivalence of the proposed design.
- A testing of lever-out, push- out and torsional resistance demonstrating that the proposed worst- case scenario met the prescribed acceptance criteria. Additionally a gap analysis justified the decreased wear rates.

Results of engineering studies referenced in this 510(k) submission demonstrate that the proposed Novation Crown Cup and Liners 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 W-O66-0609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Mr. Graham L. Cuthbert
Regulatory Affairs Specialist II
2320 N.W. 66th Court
Gainesville, Florida 32653

MAY 2 7 2010

Re: K100269
Trade/Device Name: Exactech® Novation® Crown Cup® and Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prothesis
Product Code: LPH, LZO, LWJ, JDI, MEH
Regulatory Class: II
Dated: April 26, 2010
Received: April 29, 2010

Dear Mr. Cuthbert:

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

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

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

**510(k) Number:** K100269

**Device Name: Exactech® Novation® Crown Cup® and 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.
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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)**

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

510(k) Number K100269