Exactech® Novation® Crown Cup® with InteGrip™
Special 510(k) – 510(k) Summary of Safety and Effectiveness

K102975

NOV - 5 2010

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

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

Contact: Vladislava Zaitseva
Regulatory Affairs Specialist

Date: November 5, 2010

Trade of Proprietary or Model Name(s):
Exactech® Novation® Crown Cup® with InteGrip™ Acetabular Shell

Common Name:
Total Hip Arthroplasty – Acetabular Components

Classification Name:
21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Class II. Product Code: LPH – prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented.

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade of Proprietary Model Name	Manufacturer
K070479	Novation® Crown Cup™ and Liners	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. 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.

Device Description:
The proposed Novation Crown Cup with InteGrip acetabular shells are modifications to the Novation Crown Cup Acetabular Shell, Cluster Hole, Plasma Coated devices cleared through premarket notification #K070479, Novation Crown Cup and Liners.

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 (e.g., outer and inner geometries, constrained liner feature, apical locking feature , anti-rotational feature, and product scope)
- Material (titanium alloy)
- Shelf life (5 years)
- Packaging and sterilization materials and processes (gamma radiation sterilization to a sterility assurance level of 10^{-6}).

This submission proposes the following design change:
The proposed device will have a porous surface and will be manufactured from titanium alloy per ISO 5832-3 using an additive manufacturing process. The same material surface/coating was previously cleared for porous uncemented use in the hip in 510(k) K101761 - Exactech Novation Empire Acetabular Augments with InteGrip.

Substantial Equivalence Conclusion:
The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed device to the predicate Novation Crown Cup acetabular shells:
- Abrasion resistance (ASTM F1978-07), shear fatigue strength (ASTM F1160-50), static shear strength (ASTM F1044-08), static tensile strength (ASTM F1147-05) and compressive deformation testing was conducted to evaluate the integrity of the porous surface/coating.
- Testing was performed to demonstrate the porous surface/coating met the specifications of 21 CFR 888.3358 (i.e., volume % porosity [ASTM F1854-01], pore size [ASTM F1854-01], thickness (ASTM F1854-01], interconnected porosity) for a porous-coated uncemented hip prosthesis.
- A 12-week ovine animal study to indicate that stable fixation occurs via biological fixation and is comparable to predicate devices.

These engineering analyses were originally provided and reviewed in premarket notification K101761 - Exactech Novation Empire Acetabular Augments with InteGrip. The results of engineering analyses demonstrate the proposed device is substantially equivalent to the predicate device.

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. Vladislava Zaitseva
Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

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Re: K102975
Trade/Device Name: Exactech Novation Crown Cup with InteGrip Acetabular Shell
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: LPH, JDI, KWZ, LZO
Dated: October 5, 2010
Received: October 6, 2010

Dear Ms. Zaitseva:

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

Exactech® Novation® Crown Cup® with InteGrip™
Special 510(k) – Indications for Use

NOV - 5 2010

510(k) Number: K102975

Device Name: Exactech® Novation® Crown Cup® with InteGrip™ Acetabular Shell

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 **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 K102975