K083392 # 1/2

Exactech® Novation® Cemented Plus Femoral Stems
Special 510(k) – 510(k) Summary of Safety and Effectiveness

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

DEC 17 2008

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

Contact: **Graham L. Cuthbert**
Regulatory Affairs Specialist

Date: November 14, 2008

Trade or Proprietary or Model Name(s):
Exactech® Novation® Cemented Plus Femoral Stems

Common Name:
Cemented Femoral Hip Prosthesis

Classification Name:
Prosthesis, hip, semi-constrained, metal/polymer, cemented

Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

Information on devices to which Substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K052787	Novation® 12/14 Cemented Femoral Stems	Exactech, Inc.

K083592 + 2/2

Exactech® Novation® Cemented Plus Femoral Stems
Special 510(k) – 510(k) Summary of Safety and Effectiveness

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 Cemented Plus femoral stem is a modification to the existing Novation Cemented femoral stem devices previously cleared in K052787. The proposed stem has the same general design features (collar, cement groove, and "cobra" flange) as the predicate stem, but incorporates a more trapezoidal distal geometry. Additionally, the proposed device includes 5 additional sizes (standard offset Size 10, standard and extended offset Size 12 and 14) to the scope. The proposed stems mate with previously cleared 12/14 CoCr (#K041906), Zirconia ceramic (#K060107), and Alumina ceramic (#K032964 and #K051682) femoral heads.

The predicate and proposed devices have the same intended use and basic fundamental scientific technology and share the following similarities:
• the same indications for use
• the same design features
• incorporate the same materials
• the same shelf life
• are packaged and sterilized using the same materials and processes.

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate that the proposed Novation Cemented Plus femoral stem is substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC 17 2008

Re: K083392
Trade/Device Name: Exactech® Novation® Cemented Plus Femoral Stems
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
Dated: November 14, 2008
Received: November 17, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Exactech® Novation® Cemented Plus Femoral Stems
Special 510(k) – Indications for Use

510(k) Number: K083392

Device Name: Exactech® Novation® Cemented Plus Femoral Stems

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 General, Restorative,
and Neurological Devices

510(k) Number K083392