K090764 (pg 1/2)

Exactech® Novation® CFS™ Press-Fit and Cemented Femoral Stems
Special 510(k) – 510(k) Summary of Safety and Effectiveness

APR 21 2009

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

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FDA Establishment Number 1038671

Contact: Tara R. Patterson
Associate Regulatory Affairs Specialist

Date: March 18, 2008

Trade or Proprietary or Model Name(s):
Exactech® Novation® CFS™ Press-Fit and Cemented Femoral Stems

Common Name:
Cemented Femoral Hip Prosthesis

Press-Fit Femoral Hip Prosthesis

Classification Name:

Prosthesis, hip, semi-constrained, metal/polymer, uncemented

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
K042842	Novation® 12/14 Press-Fit Femoral Stems	Exactech, Inc.
K083392	Novation® Cemented Plus Femoral Stems	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

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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 CFS Press-Fit and Cemented Femoral Stems are modifications to the existing Novation Press-Fit and Novation Cemented Plus femoral stem devices previously cleared in K042842 and K083392, respectively. The proposed Novation CFS Press-Fit stem has the same general design features as the predicate device. The modifications include the addition of a calcar collar, grit-blast body, and a satin finish neck. The proposed CFS Cemented stem has the same general design features as the Novation Cemented Plus stem, but the proposed stems are cast instead of forged cobalt chrome alloy and the neck is a satin finish. Both proposed stems contain a modified 12/14 femoral head taper connection.

The proposed stems mate with previously cleared 12/14 Co-28Cr-6Mo femoral heads (K041906), Zirconia ceramic femoral heads (K050398 and K060107) and 12/14 Unipolar Sleeves (K010081). The proposed stems are not compatible with alumina ceramic femoral heads (K032964 and K051682).

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
• similar 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 CFS Press-Fit and Cemented Femoral Stems are 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

APR 21 2009

Exactech® Inc.
% Ms. Tara R. Patterson
Associate Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, FL 32653

Re: K090764
Trade/Device Name: Novation CFS Press-Fit and Cemented Stems
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: LWJ, LZO, JDI
Dated: March 19, 2009
Received: March 23, 2009

Dear Ms. Patterson:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D Rumm MD
Dep Director

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

Enclosure

Exactech® Novation® CFS™ Press-Fit and Cemented Femoral Stems
Special 510(k) – Indications for Use

510(k) Number: K090764 (pg 1/1)

Device Name: Exactech® Novation® CFS™ Press-Fit and Cemented 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__ (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090764