Summary of Safety and Effectiveness
Special 510(k)

K080980 (pg 1/3)

Sponsor: Exactech® Inc.
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MAY - 6 2008

FDA Establishment Number 1038671

Contact: Xavier Sarabia
Director of Regulatory Affairs

Date: April 1, 2008

Summary of Safety and Effectiveness
Special 510(k) K080980 (pg 2/3)

Trade or proprietary or model name(s):

Novation Element Press-Fit Femoral Stem

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K990197	HA coated MCS Total Hip System	Exactech, Inc.
K041906	12/14 Acumatch Press-Fit Femoral Stem	Exactech, Inc.

DESCRIPTION OF DEVICE MODIFICATIONS
The proposed Exactech Novation Element Press-Fit Femoral Stem is a modification of the HA Coated MCS Total Hip System cleared through premarket notification #K990197 and 12/14 Acumatch Press-Fit Femoral Stem cleared through premarket notification #K041906.

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 basic design features
- incorporate the same materials
- the same shelf life
- are packaged and sterilized using the same materials and processes

The only modifications to the technological characteristics of the predicate devices are:

- The trapezoidal cross-sectional geometry of the shaft has been slightly altered.
- Horizontal grooves have been added to the shaft

Standard orthopedic instrumentation (FDA class I) is used for implantation of the Novation Element Press-Fit Femoral Stem. These press-fit femoral components are designed such that an interference condition is created between the implant and host bone.

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.

The Novation Element Press-Fit Femoral Stem is intended for press-fit fixation.

Substantial Equivalence

Testing and engineering evaluations were conducted verifying that the performance of the new Novation Element Press-Fit Femoral Stem is adequate for anticipated *in vivo* use. In addition to the design similarities listed above, these results demonstrate that the proposed device is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Exactech® Inc.
% Mr. Xavier Sarabia
Director of Regulatory Affairs
2320 N.W. 66th Court
Gainesville, FL 32653

MAY - 6 2008

Re: K080980
Trade/Device Name: Exactech Novation Element Press-Fit Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained or non porous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: April 1, 2008
Received: April 7, 2008

Dear Mr. Sarabia:

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

Enclosure

Exactech®, Inc.

Exactech Novation Element Press-Fit Femoral Stems

Indications for Use

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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.

Novation Element press-fit femoral stems with HA coating are intended for press-fit fixation.

Prescription Use ___X___ **or** **Over the Counter Use** _____

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for M.K.M.

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

510(k) Number K080980