Exactech®

K042842

NOV - 9 2004

Exactech®
Novation 12/14 Press-Fit Femoral Stems

510(k) Summary of Safety and Effectiveness
Special 510(k)

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

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

Contact: Gary J. Miller
Exec. V.P. of Research & Development

Date: October 7, 2004

K042842

Exactech®
Novation 12/14 Press-Fit Femoral Stems

510(k) Summary of Safety and Effectiveness
Special 510(k)

Trade or proprietary or model name(s):

Novation 12/14 Press-Fit Plasma Femoral Stems

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
#K041906	AcuMatch P-Series Plasma Press-Fit 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 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® press-fit femoral stems are intended for press-fit fixation.

Press-fit femoral stems without hydroxyapatite (HA) coating may also be used with bone cement at the discretion of the surgeon.

Device Description:

The proposed Exactech Novation 12/14 Press-Fit Femoral Components are a modification of the AcuMatch P-Series Plasma Press-Fit Femoral Stems cleared through premarket notifications #K041906.

The predicate and proposed products have the same intended use and the same basic fundamental scientific technology.

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The modified Novation femoral stems share the following similarities to the predicate AcuMatch femoral stems:

- the same indications for use,
- similar design features (e.g. neck angle, femoral head taper design (12/14), neck flat geometry (angled), offsets - standard and extended).
- the same materials (titanium alloy, commercially pure titanium plasma spray and hydroxyapatite coating)
- the same shelf life (5 years), and
- are packaged and sterilized using the same materials and processes (gamma radiation sterilization to a sterility assurance level (SAL) of 10^{-6}).

This Special 510(k) application supports the following design changes:

- The trapezoidal cross-sectional area was modified to a circulo-trapezoidal geometry.
- A change to the sizing range and differential.
- A distally "splined" model was added to the product line.
- Change in plasma coating application area.

Substantial Equivalency Conclusion:

A risk analysis was performed to assess the impact of the modifications on the safety of the Novation femoral stem design. Based on successful completion of design control activities for the Exactech Novation 12/14 Press-Fit Plasma Femoral Stems, we propose that they are substantially equivalent to the Exactech AcuMatch 12/14 P-Series Plasma Press-Fit Femoral Stems cleared through premarket notification #K041906. Supporting verification activities include ISO 7206-8 empirical fatigue testing and engineering analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2004

Gary J. Miller, Ph.D.
Executive Vice President of Research & Development
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K042842
Trade/Device Name: Novation 12/14 Press-Fit Femoral Stems
Regulation Number: 21 CFR 888.3353, 888.3350
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LZO, MEH, LWJ, JDI
Dated: October 8, 2004
Received: October 14, 2004

Dear Dr. Miller:

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.

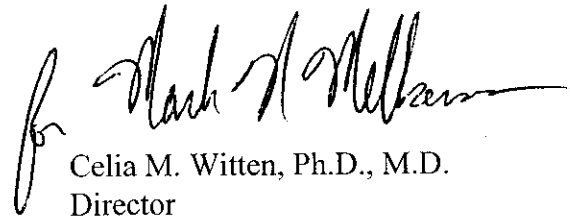
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech®

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GAINESVILLE, FL 32653
352 377 1140
FAX 352-378-2617

Exactech®, Inc.

Indications for Use

510(k) Number (if known): K042842

Device Name: Novation 12/14 Press-Fit Femoral Stems

INDICATIONS FOR USE:

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Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(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