

K102487

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**Exactech® Novation® Tapered 12/14 Press-Fit Femoral Stems
Special 510(k) – 510(k) Summary of Safety and Effectiveness**

NOV 8 2010

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

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FDA Establishment Number 1038671

Contact: Vladislava Zaitseva
Regulatory Affairs Specialist

Date: October 12, 2010

Trade or Proprietary or Model Name(s):
Exactech® Novation® Tapered 12/14 Press-Fit Femoral Stems

Common Name:
Press-Fit Femoral Stem component

Classification Name:

- Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented. (CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II, Product Code LZO)
- Prosthesis, hip, semi-constrained, metal/polymer, uncemented. (CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis Class II, Product Code LWJ)
- Prosthesis, hip, semi-constrained, metal/polymer, cemented. (CFR 888.3350. Hip joint metal/polymer semi-constrained cemented prosthesis Class II, Product Code JDI)

Information on devices to which substantial equivalence is claimed:

<u>510(k) Number</u>	<u>Trade or Proprietary or Model Name</u>	<u>Manufacturer</u>
K042842	Novation 12/14 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

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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 Exactech Novation Tapered 12/14 Press-Fit Femoral Stems are a modification of the Exactech Novation 12/14 Press-Fit Femoral Stems cleared through premarket notification #K042842.

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

The modified devices share the following similarities with predicate devices:

- The same indications for use
- The same design features (e.g. neck and stem geometry, femoral head taper design, stem insertion feature, offsets – standard and extended)
- The same materials (titanium alloy, commercially pure titanium plasma spray)
- 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 submission proposed the following design changes:

- A change to the sizing range and increments between additional femoral stem sizes
- A heat treatment change for the additional femoral stem sizes only

Substantial Equivalence Conclusion:

The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed device to the predicate Novation Tapered 12/14 Press-Fit Femoral Stems:

- An engineering evaluation to determine that the geometric features of the proposed device correspond to the anatomical features of the femur.
- An engineering evaluation to determine that the proposed device has fatigue strength equivalent to other comparable legally marketed femoral stems.

The results demonstrate that the proposed device is a 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 Northwest 66th Court
Gainesville, Florida 32653

NOV - 8 2010

Re: K102487

Trade/Device Name: Exactech[®] Novation[®] Tapered 12/14 Press-Fit 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, LWJ

Dated: October 12, 2010

Received: October 15, 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

K102487

Exactech® Novation® Tapered 12/14 Press-Fit Femoral Stems
Special 510(k) – Indications for Use

510(k) Number: _____

NOV -- 8 2010

Device Name: Exactech® Novation® Tapered 12/14 Press-Fit 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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K102487 *Barbara Bennett*
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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