K063279

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Exactech® Novation Splined RDD Femoral Stems

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

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

Phone: (352) - 377 - 1140
Fax: (352) - 378 - 2617

FDA Establishment Number 1038671

Contact: Maritza Elias
Regulatory Representative

Date: October 13, 2006

Exactech® Novation Splined RDD Femoral Stems

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

Trade or proprietary or model name(s):

Novation Splined RDD Femoral Stems

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.

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 Splined RDD Press-Fit Femoral Stem is a modification of the predicate Novation 12/14 Splined Press-Fit Femoral Stems cleared through premarket notification #K042842. Both products share the same intended use and basic fundamental scientific technology and differ only in the proposed reduced distal cross-sectional diameter.

Exactech® Novation Splined RDD Femoral Stems

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Substantial Equivalency Conclusion:

Engineering evaluations were conducted to verify that the performance of the proposed Novation Splined RDD Femoral Stems would be adequate for anticipated *in vivo* use. Based on successful results discussed in this submission, we conclude that the proposed devices are substantially equivalent to Exactech's predicate femoral stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2006

Exactech, Inc.
c/o Ms. Maritza Elias
Regulatory Representative
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K063279
Trade/Device Name: Novation Splined Reduced Distal Diameter (RDD) Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, MEH, LWJ, and JDI
Dated: October 13, 2006
Received: October 31, 2006

Dear Ms. Elias:

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

Sincerely yours,

Barbara Brehm

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

Enclosure

K063279

Exactech® Novation Splined RDD Femoral Stems

Special 510(k) – Indications for Use

510(k) Number (if known):

Device Name: Novation Splined RDD 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)

Barbara Brochus

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

510(k) Number K063279