2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

Exactech® Novation Crown Cup™ and Liners
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

MAR 15 2007

FDA Establishment Number 1038671

Contact: Maritza Elias
Regulatory Representative

Date: February 12, 2007

Exactech®
2320 NW 66TH COURT
GAINESVILLE, FL 32653
352-377-1140
FAX 352-378-2617

Exactech® Novation Crown Cup™ and Liners
Special 510(k) - 510(k) Summary of Safety and Effectiveness

Trade or proprietary or model name(s):

Novation Crown Cup and Liners

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
#K993082	AcuMatch A-Series Porous Coated Cups and Liners	Exactech, Inc.
#K000242	AcuMatch A-Series Corundum Cups	Exactech, Inc.
#K051556	AcuMatch A-Series GXL Liners	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 Crown Cups™ and Liners are modifications of the previously cleared AcuMatch A-Series predicates. The design features of the subject devices are summarized below:

NOVATION CROWN CUP AND LINERS

- No-Hole and Cluster Hole design options
- Shells manufactured from titanium (Ti) alloy with plasma coating and an additional hydroxylapitite (HA) coating option
- Sphere and taper inner diameter geometry

Exactech®
2320 NW 66TH COURT
GAINESVILLE, FL 32653
352-377-1140
FAX 352-378-2617

Exactech® Novation Crown Cup™ and Liners
Special 510(k) - 510(k) Summary of Safety and Effectiveness

Substantial Equivalency Conclusion:

Engineering evaluations were conducted to verify that the performance of the proposed acetabular components 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 the previously cleared predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2007

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

Re: K070479
Trade/Device Name: Novation Crown Cups and Liners
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, MEH, LPH
Dated: February 12, 2007
Received: February 20, 2007

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 Bucher
for

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

Enclosure

Exactech® Novation Crown Cup™ and Liners
Special 510(k) – Indications for Use

510(k) Number (if known):

Device Name: Novation Crown Cup™ and Liners

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.

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 Bucher MD

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

510(k) Number K070479