Exactech®
Ziramic™ Zirconia 12/14 Femoral Heads
Special 510(k) -Summary of Safety and Effectiveness

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

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

Contact: **Maritza Elias**
Regulatory Representative

Date: **February 2, 2006**

Exactech®
Ziramic™ Zirconia 12/14 Femoral Heads
Special 510(k) -Summary of Safety and Effectiveness

Trade / Proprietary Name:	Exactech ®
Model Name:	Ziramic™ Zirconia 12/14 Femoral Head
Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Product Code:	LZO, LPH
C.F.R. Section:	21 CFR 888.3353, 21 CFR 888.3358
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Exactech® Ziramic™ Zirconia 12/14 Femoral Head #K050398

Device Description:

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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CONTRAINDICATIONS
Exactech Hip Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

The Zirconia Ceramic Head is contraindicated for use with any other acetabular cup liner than an ultra high molecular weight polyethylene (UHMWPE) liner or a metal backed UHMWPE liner.

The safety and effectiveness has not been shown for the use of Exactech stems when used with ceramic on ceramic acetabular cups.

Special 510(k) Modifications
The Exactech® Ziramic™ Zirconia 12/14 Femoral Heads were modified from the predicate as follows:

- The mating parts scope was expanded to include:
  Exactech® AcuMatch® 12/14 Cemented Femoral Stems
  Exactech® Novation™ 12/14 Cemented Femoral Stems

- The package insert was updated to clarify femoral head and femoral stem compatibility

Conclusion:
Testing and engineering evaluations were conducted to verify adequate performance of the Exactech® Ziramic™ Zirconia 12/14 Femoral Heads for anticipated *in vivo* loading when mated with Exactech cobalt chrome alloy 12/14 Femoral Stems. Based on successful results we conclude that the proposed 12/14 Ziramic™ Zirconia 12/14 Femoral Heads devices are substantially equivalent to the predicate design (#K050398).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 2006

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

Re: K060107
Trade/Device Name: Ziramic™ Zirconia 12/14 Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Regulatory Class: II
Product Codes: LZO, LPH
Dated: December 16, 2005
Received: January 13, 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Exactech®, Inc.
Ziramic™ Zirconia 12/14 Femoral Heads
Special 510(k) – Indication for Use

510(k) Number: K060107

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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)

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

510(k) Number K060107