

K050398 P1/3

NOV 18 2005

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
Fax: (352) - 378 - 2617

FDA Establishment Number 1038671

Contact: Maritza Elias
Regulatory Representative

Date: November 15, 2005

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 12/14 Alumina Ceramic Femoral Head #K032964

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.

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

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.

Exactech 12/14 Zirconia Ceramic Femoral Heads

This Special 510(k) application supports the substantial equivalency of the Ziramic™ Zirconia (Zyranox®) 12/14 Femoral Heads relative to Exactech's predicate 12/14 Alumina (BIOLOX® forte) Ceramic Femoral Heads (#K032964). The design modifications include a change in the ceramic material composition from alumina to zirconia, and the addition of +7mm and +10 mm skirted heads for the 28mm, 32 mm and 36 mm outer diameter sizes.

The proposed Ceramic Femoral Heads are composed of Morgan Advanced Ceramic's Zyranox® zirconia material and have a European 12/14 taper design. The material properties of Zyranox® are described in FDA Master File MAF-343.

Conclusion:

Testing and engineering evaluations were conducted to verify that the performance of the new 12/14 zirconia ceramic femoral heads would be adequate for anticipated *in vivo* loading when mated with Exactech titanium 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 Exactech's predicate 12/14 Alumina Femoral Heads (#K032964).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2005

Maritza Elias
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K050398

Trade/Device Name: Exactech Ziramic™ Zirconia 12/14 Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented
or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, LPH
Dated: October 28, 2005
Received: November 1, 2005

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: K050398

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.

CONTRAINDICATIONS

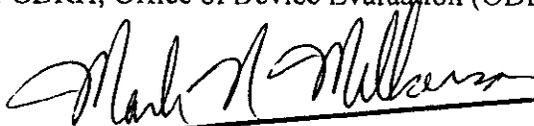
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Prescription Use X or Over the Counter Use _____

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 K050398