Exactech®

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K020291

Exactech® Femoral Stem Centralizers

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

FEB 2 7 2002

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

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

Contact: Robert Paxson
Director of Engineering & Development

Date: January 24, 2002

K020291

Exactech® Femoral Stem Centralizers

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

Classifications / Proprietary Names:

Name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (Centralizer Component)
Product Code:	JDI
C.F.R. Section:	888.3350
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer
Total Hip System	Exactech, Inc.
VerSys	Zimmer
Answer	Biomet

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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Exactech® Femoral Stem Centralizers

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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 L-Series unipolar is also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.

DESIGN

The Exactech centralizers are designed to provide central placement of Exactech cemented stems within the femoral canal.

The components have three fins and a tapered post for attachment to Exactech cemented femoral components. The device is composed of polymethylmethacrylate (PMMA) and comes in sizes ranging from 7mm to 17mm in diameter.

UTILIZATION

Selection of the centralizer component is made by the surgeon in relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prosthesis by: 1) appropriate reading of the literature and 2) training in the operative skills and techniques required for hip arthroplasty surgeries.

SUBSTANTIAL EQUIVALENCY

The proposed Exactech Centralizers are similar in design and material specifications to other products legally marketed in the United States, most notably Exactech's predicate centralizer design cleared through premarket notification #K862234.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

Mr. Robert Paxson
Director of Engineering & Development
Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K020291
Trade/Device Name: Exactech® Femoral Stem Centralizer
Regulation Number: 21 CFR 888.3350
Regulation Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Regulatory Class: Class II
Product Code: JDI
Dated: January 25, 2002
Received: January 28, 2002

Dear Mr. Paxson:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech®
Femoral Stem Centralizers

Indications for Use

510(k) Number: K020291

Device Name: Exactech® Femoral Stem Centralizer

INDICATIONS
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for Mark N Melkerson

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

510(k) Number K020291

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____