Exactech®

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K030236

Exactech® AcuMatch™ Integrated Hip System
P-Series Porous Femoral Components

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

FEB 2 0 2003

Sponsor: Exactech® Inc.
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FDA Establishment Number 1038671

Contact: Gary J. Miller, Ph.D.
Exec. V.P. of Research and Development

Date: January 20, 2003

Exactech® AcuMatch™ Integrated Hip System
P-Series Porous Femoral Components

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

Classifications / Proprietary Names:

Classification Names:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous, Uncemented (Femoral Component)
Product Code:	LPH
Trade / Proprietary Model Names:	AcuMatch P-Series Porous Press-Fit Femoral Component
C.F.R. Section:	888.3358
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer	510(k) Number
AcuMatch P-Series Plasma Femoral Stem	Exactech	K002141
MCS Porous Femoral Stem	Exactech	K921113 K990197
AML Porous	Depuy	K003800 K012364
Synergy Porous	Smith & Nephew	K991485 K002996

Exactech® AcuMatch™ Integrated Hip System
P-Series Porous Femoral Components

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Device Description:

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.

AcuMatch Press-Fit components are intended for use in press-fit applications. Components without the optional hydroxyapatite (HA) coating may also be used with bone cement.

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.

Design Features
AcuMatch P-Series Porous Femoral Stems are composed of titanium alloy (Ti-6Al-4V) conforming to ASTM F1472-99. The stems have a trapezoidal cross-sectional geometry, distal taper, and calcar collar option. There are two offset options available. The porous bead coating on the proximal portion of the stem is composed of titanium beads meeting the specifications of ASTM F67-95, Grade 2. An optional hydroxyapatite (HA) coating is also available. The products are provided as sterile, single use only with a sterility assurance level (SAL) of 10^{-6}.

Substantial Equivalency
AcuMatch P-Series Porous stems are substantially equivalent to other femoral components, most notably the Exactech MCS and P-Series Plasma stems. The predicate and proposed devices share common design features and material properties. Fatigue testing was performed to verify that the implant performance would be adequate for anticipated *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Ms. Lisa Simpson
Sr. Regulatory Representative
Exactech
2320 NW 66th Court
Gainesville, FL 32653

Re: K030236
Trade/Device Name: AcuMatch P-Series Porous Press-Fit Femoral Component
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: January 20, 2003
Received: January 23, 2003

Dear Ms. Simpson:

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 (301) 594-4639. 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 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 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® AcuMatch™ Integrated Hip System
P-Series Porous Press-Fit Femoral Components

Indications for Use

510(k) Number: K030236

Device Name: AcuMatch P-Series Porous
Press-Fit Femoral Stem

Indications for Use:

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

510(k) Number K030236 Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over the Counter Use No