Exactech®

2320 NW 66TH COURT
GAINESVILLE, FL 3265
352-377-1140
FAX 352-378-2617

K012493

AUG 2 9 2001

Exactech® AcuMatch™ Integrated Hip System

C Series Cemented Femoral Component – Size 0

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: **Robert Paxson**
Director of Engineering & Development

Date: **July 17, 2001**

Exactech® AcuMatch™ Integrated Hip System
C-Series Cemented Femoral Component – Size 0

510(k) Summary of Safety and Effectiveness

Product Classification:

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

510(K) Information – Predicate Devices

Model	Manufacturer	510(k)#
AcuMatch L-Series	*Exactech*	*#K001335, #K011218*
AuRA	*Exactech*	*#K961304*
Conquest FX	Smith & Nephew	
Spectron	Smith & Nephew	
PFC	Depuy	

Substantial Equivalence Information:

The Exactech AcuMatch C-Series Cemented Femoral (size 0) component has similar indications and contraindications as other femoral components legally marketed in the United States. In addition the C-Series has similar technological features to other devices, most notably Exactech's AuRA and L-Series femoral components. In addition, the proposed C-Series component is similar to femoral components currently marketed by other manufacturers. These include the "Conquest FX" and "Spectron" by Smith & Nephew and the "PFC" by Depuy.

Exactech® AcuMatch™ Integrated Hip System

C-Series Cemented Femoral Component – Size 0

510(k) Summary of Safety and Effectiveness

Intended Use / Indications:

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, 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 revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

The AcuMatch C-Series Femoral component is intended to 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.

Device Description:

C-Series Femoral Stem Components are made from Cobalt Chromium Molybdenum alloy forged per ASTM F 799-96. The components have a satin finish and are intended for cemented applications only. The stems have a collar to enhance cement pressurization and stress transmission to the medial femoral neck. There is a proximal to distal taper and trapezoidal cross-sectional geometry in the distal region. C-Series stems may be used with optional distal PMMA centralizers to ensure central stem placement.

Performance Data Summary:

Three point bending fatigue testing showed that the strength of the C-Series size 1 components is sufficient to support expected *in vivo* load applications.

510(k) Summary of Safety and Effectiveness

Packaging Materials:

Material	Composition
Inner / Outer Trays	PETG – 0.040" thickness (before forming)
Tray Lids	1073B Dupont Tyvek® w/HSC Coating
Inserts	Crosslinked Plastizote LD45 Foam
Box	35-40 point Clay Coated News
Outer Shrink-Wrap	Clear, Light-Weight PE
Shipping Cartons	Heavy-weight Corrugated Cardboard

Sterilization Specifications:

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): 10^{-6}

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2001

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

Re: K012493
Trade Name: AcuMatch C-Series Cemented Femoral Component, Model size "0"
Regulation Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: June 21, 2001
Received: June 25, 2001

Dear Ms. Simpson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

Enclosure

Exactech® AcuMatch™ Integrated Hip System

Indications for Use

510(k) Number: K012493

Device Name: Exactech® AcuMatch™ Integrated Hip System
C-Series, Size 0 Cemented Femoral Stem Component

Indications for Use:

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for Mark N Milleman

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

510(k) Number K012493

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