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SEP 10 2004

# Exactech®
# 12/14 Total Hip System

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

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

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

**Contact:** Gary J. Miller
Exec. V.P. of Research & Development

**Date:** August 17, 2004

**Exactech®**
**12/14 Total Hip System**

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

**Trade or proprietary or model name(s):**

AcuMatch 12/14 Press-Fit Femoral Stems
AcuMatch 12/14 CoCr Femoral Heads
AcuMatch A-Series Acetabular Component (36mm I.D.)

**Information on devices to which substantial equivalence is claimed:**

| 510(k) Number | Trade or Proprietary or Model Name | Manufacturer |
|---|---|---|
| K030236 | AcuMatch P-Series Press-Fit Porous Femoral Stem | Exactech, Inc. |
| K002141 | AcuMatch P-Series Press-Fit Plasma Femoral Stem<br>AcuMatch L-Series Press-Fit Femoral Stem | Exactech, Inc. |
| K862234 | Exactech CoCr Femoral Head | Exactech, Inc. |
| K964262 | Exactech CoCr Femoral Head | Exactech, Inc. |
| K993082 | AcuMatch A-Series Acetabular Liners | Exactech, Inc. |

**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.

AcuMatch® P-Series and AcuMatch® L-Series press-fit femoral stems are intended for press-fit fixation.

AcuMatch® A-Series press-fit acetabular cups are intended for press-fit fixation.

Press-fit acetabular shells and press-fit femoral stems without hydroxyapatite (HA) coating may also be used with bone cement at the discretion of the surgeon.

Cobalt chromium femoral heads are intended for use in cemented and press-fit applications.

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**Special 510(k) Device Modifications**
The femoral stem tapers on predicate Exactech total hip system components were modified from a proprietary Exactech design to a "12/14 Euro-style" design. A 36 mm line of femoral heads and mating acetabular liners was also added to the system. As such, each component covered in the "Special 510(k)" represents a design change to an Exactech predicate device.

**12/14 CoCr Femoral Heads**
12/14 CoCr Femoral Heads are composed of cobalt chromium alloy conforming to ASTM F1537 (warm worked condition). The femoral stem taper connection was modified from a proprietary Exactech taper design to a 12/14 Euro-style taper design. This allows for compatibility with Exactech 12/14 femoral stem components.

**AcuMatch 12/14 Press-Fit Femoral Stems**
AcuMatch 12/14 Press-Fit femoral stems are composed of titanium alloy (ASTM F1472), have a trapezoidal cross-sectional geometry and distal taper. The P-Series model is available with a porous bead or plasma-spray surface enhancement. The L-Series model has a corundum finish. Options include collared and non-collared versions and hydroxapatite (HA) coating. The components are intended for press-fit applications.

The AcuMatch Press-Fit femoral stems were modified as follows:
- The femoral neck length was decreased by 4mm
- The femoral neck geometry was shifted medially by 1.5 mm
- The geometry of the insertion hole feature was modified from a dimple to the oblong slot.
- "12/14" Laser-etching was added to the face of the femoral stem taper.
- A "High Offset" version was added to the P-Series Plasma product line.

**36 mm AcuMatch A-Series Acetabular Liners**
The A-Series 36mm liners are a line extension to the current A-Series product line. The new liners are designed to mate with A-Series Acetabular "shell" components. This includes the A-Series Porous Acetabular Shells (K993082) and the A-Series Corundum Acetabular Shell (K000242). Each liner has a size designation (H, J, or K) that matches it to the correct mating shell component. The new 36 mm A-Series Acetbular liners are designed to articulate with the Exactech 12/14 36mm cobalt chromium femoral heads.

All Exactech implant components are provided as sterile, single use only to a sterility assurance level (SAL) of $10^{-6}$.

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**Conclusion:**
Testing and engineering evaluations were conducted to verify that the performance of the new Exactech 12/14 Total Hip System components would be adequate for anticipated *in vivo* use. This includes empirical testing and engineering analyses. Based on successful results we conclude that the proposed devices are substantially equivalent to Exactech's predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2004

Gary J. Miller, Ph.D.
Executive Vice President of Research & Development
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K041906
Trade/Device Name: Exactech 12/14 Total Hip System
Regulation Number: 21 CFR 888.3358, 888.3353, 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, MEH, LWJ, JDI
Dated: August 17, 2004
Received: August 19, 2004

Dear Dr. Miller:

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.

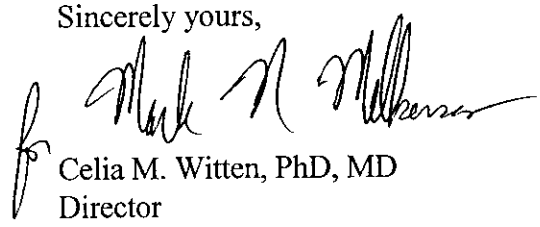
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K041906

# Exactech®, Inc.

## Exactech 12/14 Total Hip System

## Indications for Use

**510(k) Number:** **#K041906**

**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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Cobalt chromium femoral heads are intended for use in cemented and press-fit applications.

**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)

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

**510(k) Number** K041906