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JUN 0 4 2004

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By:

Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

2. Contact:

Dr. Gary Miller
Executive Vice President of Research and Development
Exactech, Inc.
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Gainesville, FL 32653
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3. Product:

Exactech AcuMatch A-Series® and MCS® Acetabular Shells and Liners

21 CFR Section 888.3358
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Class II

Product Codes JDI, LPH, MEH

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Description:

Exactech AcuMatch A-Series® & MCS® Acetabular Shells and Liners are designed for use with appropriately sized Exactech femoral stems and heads.

The metal shells are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. They are porous coated with titanium beads, a blast finish, or with hydroxylapatite.

The liners are machined from compression molded ultra-high-molecular-weight polyethylene (UHMWPE). Polyethylene raw material must meet all aspects of ASTM F648.

Intended Use:

Exactech AcuMatch® A-Series and MCS® Acetabular Shells and Liners 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.

Substantial Equivalence:

The devices are line extensions, identical to previously cleared Exactech AcuMatch® (K993082 & K000242) and MCS® (K921114 & K990197) Shells and Liners.

Performance Testing:

Testing for the Exactech AcuMatch® A-Series and MCS® Acetabular Shells and Liners was performed for, and reviewed, in predicate device submissions. Design Control assessments did not indicate a need for additional testing for the line extensions which are the subject of this Special 510(k).

Conclusions:

The new sizes of Exactech AcuMatch® A-Series and MCS® Acetabular Shells and Liners are substantially equivalent to existing previously cleared devices in design, materials of construction, manufacturing, and other characteristics. The changes in the devices have been done under the control of Design Assurance, and no new unmitigated risks were identified for these line extensions. The predicate products have been shown to be an effective design, with an acceptable performance history.

The contents of this submission demonstrate that the device additions are eligible for review and clearance under the special 510(k) premarket notification process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 4 2004

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

Re: K040613
Trade/Device Name: Exactech AcuMatch® A-series and MCS® Acetabular Shells and Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JDI, LPH, MEH
Dated: May 6, 2004
Received: May 7, 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,

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

Indications for Use Statement

510(k) Number: K040613 1of1

Device Name: **Exactech AcuMatch® A-Series and MCS® Acetabular Shells and Liners**

Intended 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.

Prescription Use X or Over-the-counter use ____
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K040613