OCT 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.
2320 N.W. 66th Court
Gainesville, FL 32653
Phone: (352) 377-1140
Fax: (352) 378-2617

3. Product:
Exactech AcuMatch A-Series® & MCS®
Constrained Acetabular Liners

21 CFR Section 888.3310
Hip joint metal/polymer constrained cemented or uncemented prosthesis

Class II

Product Code 87 KWZ

Description:

Exactech AcuMatch A-Series® & MCS® Constrained Acetabular Liners are designed for use with appropriately sized Exactech AcuMatch A-Series® and MCS® acetabular shells. The Constrained Liners are designed to mechanically constrain 28mm and 32mm femoral heads by use of a constraining ring. The constraining ring is mechanically assembled to a secure Exactech® acetabular shell.

Intended Use:

Exactech AcuMatch A-Series® and MCS® constrained liners are components of the Exactech AcuMatch A-Series® or MCS® non-cemented acetabular cup system. The device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. They are intended for press-fit fixation and compatible with Exactech press-fit or cemented femoral stem components.

Technological Characteristics and Substantial Equivalence:

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

All rings are machined from titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

The devices are identical to previously cleared Exactech AcuMatch® (K993082) and MCS® (K921114) Liners except for the femoral head constraining features. The devices are similar to the Ringloc Constrained Liner (K021728) from Biomet Orthopedics and the Epsilon Durasul Constrained Acetabular Liner (K030923) from Centerpulse Orthopedics.

Performance Testing:

The Exactech AcuMatch A-Series® Constrained Acetabular Liner & MCS® Constrained Acetabular Liner have been evaluated according to FDA guidance document entitled: ***Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA***

The evaluation included a Risk Analysis and Comparison to Standards. Testing was done according to Consensus Standards.

Conclusions:

The Exactech AcuMatch A-Series® & MCS® constrained Acetabular Liners are substantially equivalent to similar devices existing in the market in materials of construction, dimensions, and performance characteristics. It has been determined to be an effective design and when used according to instructions for use, is a useful and valuable device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

Ms. Lisa Simpson
Senior Regulatory Representative
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K040601
Trade/Device Name: Exactech AcuMatch A-Series® and MCS® Constrained Acetabular Liners
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: June 30, 2004
Received: July 6, 2004

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 (240) 276-0120. 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: K040601

Device Name: **Exactech AcuMatch A-Series® & MCS® Constrained Acetabular Liners**

Intended Use: Exactech AcuMatch A-Series® and MCS® Constrained Acetabular Liners are components of the Exactech AcuMatch A-Series® or MCS® non-cemented acetabular cup system. The device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. They are intended for press-fit fixation and compatible with Exactech press-fit or cemented femoral stem components.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millhouse

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

510(k) Number K040601