K051556 p 1/3

SEP - 6 2005

Summary of Safety and Effectiveness

Exactech® AcuMatch® A-Series Enhanced Polyethylene Acetabular Liner

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

Phone: (352) - 377 - 1140
Fax: (352) - 378 – 2617

FDA Establishment #: 1038671

Contact: Diana Taylor
Regulatory Representative

Date: August 26, 2005

Trade Name: Exactech® AcuMatch® A-Series Connexion GXL Enhanced UHMWPE Acetabular Liner

Common Name: Total Hip Prosthesis Acetabular Component

Device Description:	**Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis**		
Product Code:	LPH	**C.F.R. Section**	888.3358
Device Description:	**Hip joint metal/polymer semi-constrained cemented prosthesis**		
Product Code:	JDI	**C.F.R. Section**	888.3350
Device Description:	**Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis**		
Product Code:	MEH	**C.F.R. Section**	888.3353
Device Description:	**Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis**		
Product Code:	LZO	**C.F.R. Section**	888.3353
Device Description:	**Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis**		
Product Code:	LWJ	**C.F.R. Section**	888.3360

Summary of Safety and Effectiveness

Exactech® AcuMatch® A-Series Enhanced Polyethylene Acetabular Liner

Intended Use / Indications:
AcuMatch® A-Series Enhanced Polyethylene Acetabular Liners 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.

Contraindications:
AcuMatch® A-Series Enhanced Polyethylene Acetabular liners 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.

Description:
This Special 510(k) premarket notification describes a material change from the predicate AcuMatch® A-Series UHMWPE polyethylene acetabular liners to acetabular liners manufactured from Enhanced Polyethylene. Additionally 5 new sizes are being introduced to the A-Series system.

Packaging and Sterilization:
AcuMatch® A-Series Enhanced UHMWPE Acetabular liners are sealed in two Tyvek® pouches. The pouches are enclosed in a poly bag and placed into the outer carton. A tamper-resistant seals on the outer box contain the statement "sterile unless seal is broken". An outer product label is attached to the outer carton. The carton is then shrink-wrapped.

Products are terminally sterilized by a precision gamma irradiation dose of 25.2 – 30.8 kGy. The Sterility Assurance Level (SAL) is 10^{-6}.

Summary of Safety and Effectiveness

Exactech® AcuMatch® A-Series Enhanced Polyethylene Acetabular Liner

Legally Marketed Predicate Devices

Model	Manufacturer	510(k) #	Clearance Date	Product Code(s)
AcuMatch® A-Series Porous Coated Acetabular Component	Exactech	K993082	11/19/1999	LPH & JDI
AcuMatch® A-Series and MCS Acetabular Shells & Liners	Exactech	K040613	06/4/2004	JDI, LPH & MEH
AcuMatch® A-Series 36mm Acetabular Liner, 12/14 Femoral Head and Press-Fit Femoral Stems	Exactech	K041906	09/10/2004	LPH, LZO, MEH, LWJ & JDI

Conclusion:
The proposed AcuMatch® A-Series Enhanced Polyethylene Acetabular Liners are substantially equivalent to the predicate AcuMatch® A-Series Acetabular Liners of the same design, which have not had additional processing of the material. The proposed liners manufactured from enhanced material are expected to exhibit reduced wear, while maintaining suitable mechanical and physical properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Ms. Diana Taylor
Manager, Regulatory Affairs
Exactech®, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K051556
Trade/Device Name: AcuMatch® A-Series Enhanced Polyethylene Acetabular Liners
Regulation Number: 21 CFR 888.3358, 21 CFR 888.3350, 21 CFR 888.3353, 21 CFR 888.3360
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Regulatory Class: II
Product Code: LPH, JDI, LZO, MEH, LWJ
Dated: August 09, 2005
Received: August 10, 2005

Dear Ms. Taylor:

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.

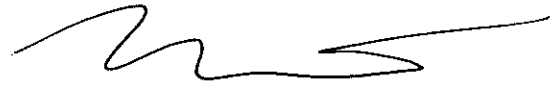
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech®, Inc.

AcuMatch® A-Series Enhanced Polyethylene Acetabular Liners

Indications for Use

510(k) Number: K051556

Device Name: AcuMatch® A-Series Enhanced Polyethylene Acetabular Liners

Indications for Use:
AcuMatch® A-Series Enhanced Polyethylene Acetabular Liners 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.

Contraindications:
AcuMatch® A-Series Enhanced Polyethylene Acetabular liners 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.

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)

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

510(k) Number K051556