K051858

P. 1/3

DEC 1 2005

Exactech®
AcuMatch M-Series LPB
12/14 Femoral Stems

Special 510(k) Summary of Safety and Effectiveness

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

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

Contact: **Michael S. Simpson**
Vice President, Regulatory and Clinical Affairs

Date: **November 30, 2005**

K051858

p. 2/3

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Special 510(k) Summary of Safety and Effectiveness

Trade or proprietary or model name(s):
AcuMatch M-Series LPB 12/14 Femoral Stem: • M-Series LPB 12/14 Neck Segment • M-Series Plasma Metaphyseal Segment • M-Series Plasma Calcar Segment • M-Series Distal Segments (Straight, Curved)

Product Classification:	**Prosthesis, hip, semi-constrained, metal/polymer, uncemented**		
Product Code:	LWJ	**C.F.R. Section**	Not specified
Classification Panel:	Orthopedic	**Device Class:**	II

Product Classification:	**Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented non-porous, uncemented**		
Product Code:	LZO	**C.F.R. Section**	888.3353
Classification Panel:	Orthopedic	**Device Class:**	II

Product Classification:	**Prosthesis, hip, semi-constrained, metal/polymer, cemented**		
Product Code:	JDI	**C.F.R. Section**	888.3350
Classification Panel:	Orthopedic	**Device Class:**	II

Information on devices to which substantial equivalence is claimed.		
510(k) Number	**Trade or Proprietary or Model Name**	**Manufacturer**
#K993736	AcuMatch M-Series Femoral Stem (S, M, L metaphyseal, calcar & distal segments)	Exactech, Inc.
#K011081	AcuMatch M-Series Femoral Stem (XS metaphyseal segments)	Exactech, Inc.
#K032964	AcuMatch M-Series Femoral Stem (12/14 neck segments)	Exactech, Inc.

Exactech®
AcuMatch M-Series LPB
12/14 Femoral Stems

Special 510(k) Summary of Safety and Effectiveness

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 M-Series LPB 12/14 Femoral Stems are intended to be used in press-fit and cemented applications.

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

The Exactech M-Series LPB 12/14 Femoral Stem is a modular four-piece system consisting of a proximal neck segment, metaphyseal segment, diaphyseal segment and metaphyseal assembly screw. All of the components are interchangeable, therefore allowing for many sizing combinations to meet varying anatomical situations. The neck segments are machined from titanium alloy bar stock or forgings (ASTM F-1472), the metaphyseal segments are machined from titanium alloy forgings (ASTM F-1472), and the distal segments are machined from titanium alloy bar stock (ASTM F-1472). The metaphyseal screws are machined from titanium alloy (ASTM F 136). The LPB system is a modification to the Exactech M-Series 12/14 Femoral Stem system cleared through premarket notifications #K993736, #K011081 and #K032964. Changes to the device relative to the predicates include minor geometry modifications, raw material manufacturing changes and application of a low-plasticity burnishing (LPB) process to the distal taper of the neck segments.

CONCLUSION

Based on a risk assessment of the design changes and successful completion of the associated verification activities, we conclude that the AcuMatch M-Series LPB 12/14 Femoral Stems are substantially equivalent to the predicate AcuMatch M-Series 12/14 Femoral Stem components cleared through premarket notifications #K993736, #K011081 and #K032964.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2005

Michael S. Simpson
Vice President, Regulatory & Clinical Affairs
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K051858
Trade/Device Name: AcuMatch M-Series LPB 12/14 Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, JDI, LWJ
Dated: November 1, 2005
Received: November 3, 2005

Dear Mr. 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.

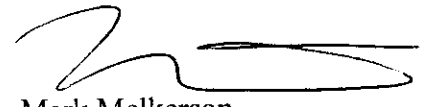
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



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

Enclosure

Exactech®, Inc.

AcuMatch M-Series LPB
12/14 Femoral Stem

Indications for Use

510(k) Number: K051858

INDICATIONS

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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 K051858