K 993736

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

JAN 20 2000

Exactech® AcuMatch™ Integrated Hip System M-Series Femoral Stem Component

510(k) Summary of Safety and Effectiveness

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

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

FDA Establishment Number 1038671

Contact: Gary J. Miller, Ph.D.
V.P. of Research and Development

Date: November 2, 1999

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Exactech® AcuMatch™ Integrated Hip System
M-Series Femoral Stem Component

510(k) Summary of Safety and Effectiveness

Trade Name:	Exactech® AcuMatch M-Series Femoral Stem Component
Common Name:	Total Hip Prosthesis Femoral Component
Classification Name:	Prothesis, Hip, Semi-Constrained, Metal/Polymer, Porous, Uncemented (Femoral Component)

Legally Marketed Devices for Substantial Equivalence Comparison:

The AcuMatch M-Series Femoral System (referred to as M-Series from this point forward) is made of similar materials and is of a similar design to other legally marketed modular femoral components. Most notably, the M-Series is equivalent in materials and design to the "S-ROM" by Joint Medical Products Corporation. The M-Series is also similar to Biomet's "Impact", Biomet's "Mallory-Head" and the "Link MP" by Link America.

Description:

The Exactech Modular Stem is a four-piece system consisting of a proximal neck segment, metaphyseal segment, diaphyseal segment and a locking screw. All of the components are interchangeable, therefore allowing for many sizing combinations to meet varying anatomical situations. The components are composed of titanium alloy.

The neck segment is available in four heights and has a male taper for attachment to the metaphyseal segment. The anteversion/retroversion adjustment of the neck is completely independent of the rest of the construction.

There are 24 sizes of plasma-coated metaphyseal segments. The bone is prepared to receive the implant using a series of milling instruments specifically designed to match the system. The proximal cross-section of this segment is trapezoidal in order to contribute torsional stability to the device. The metaphyseal segments are available in small, medium and large flare designs. A calcar version is also available.

The distal stems have parabolic distal tips, biting flutes and coronal slots. The end of the stem is polished. The stems are available in various diameters in both straight and curved designs. Each stem is interchangeable with any metaphyseal segment.

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Intended Use:

M-Series components 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 the M-Series are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

The M-Series components are indicated for press-fit and cemented applications.

Contraindications:

M-Series components 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.

Substantial Equivalence Information:

The M-Series has similar intended uses and technological features to the predicate devices. The M-Series, S-ROM, Impact, Malloy Head and Link are all used in primary and revision hip replacement surgeries.

The M-Series stem is technologically similar to the predicate stems in the use of tapered junctions in order to increase surgeon intra-operative flexibility. All of the predicate modular stems have a variation of a design which allows the surgeons to accommodate proximal / distal mismatch in the femur.

The AcuMatch M-Series stem is similar to the Biomet Mallory-Head and Impact femoral stem prosthesis in that it also uses a screw to ensure a positive lock between the stem components. The Link modular prosthesis uses the same concept except that it uses a toothed sleeve instead of a tapered junction.

All of the stems use distal flutes to further increase the rotational stability of the stem. The S-ROM, the Mallory Head, and the Impact also use a coronal slot in order to reduce distal stem stiffness.

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All stems are made of a Titanium Alloy. The Mallory-Head and Impact stems use proximal plasma coating to aid in proximal fixation. The S-ROM uses sintered titanium beads for the same purpose.

In-house endurance testing (ISO 7206-4) along with fatigue analysis by a contract testing facility shows the M-Series to be comparable to current clinically successful implants. In addition, rotational stability testing revealed that the M-Series was able to consistently withstand the torsional loads expected *in vivo*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

Ms. Lisa Simpson
Regulatory Representative
Exactech
2320 NW 66th Court
Gainesville, Florida 32653

Re: K993736
Trade Name: Exactech Integrated Hip System
M-Series Femoral Stem Component
Regulatory Class: II
Product Code: LPH/JDI
Dated: November 2, 1999
Received: November 4, 1999

Dear Ms. Simpson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® AcuMatch™ Integrated Hip System
M-Series Femoral Stem Component

Indications for Use

510(k) Number: K993736

Device Name: **Exactech Integrated Hip System**
AcuMatch M-Series Femoral Stem Component

Indications for use:

AcuMatch Integrated Hip System – M-Series Femoral Components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, osteonecrosis, congenital hip dysplasia, rheumatoid arthritis, ankylosing spondylitis, and/or post-traumatic degenerative problems. M-Series components are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present.

AcuMatch M-Series components are intended to be used in press-fit and cemented applications.

Contraindications:

AcuMatch M-Series components 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993736