

NOV 19 1999

**Exactech® AcuMatch™ Integrated Hip System
A-Series Porous Coated Acetabular Component**

510(k) Summary of Safety and Effectiveness

Trade Name: Exactech® AcuMatch A-Series
Porous Coated Acetabular Component

Common Name: Total Hip Prosthesis Acetabular Component

Classification Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer,
Porous, Uncemented (Acetabular Component)

Legally Marketed Devices for Substantial Equivalence Comparison:

The AcuMatch A-Series Acetabular System (referred to as A-Series from this point forward) is made of similar materials and is of a similar design to other legally marketed acetabular components. Most notably, the A-Series is equivalent in materials and design to the Exactech MCS Porous Cup and Exactech MCS/HA Porous Cup:

<u>Product Code</u>	<u>Model</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
LPH	MCS	Exactech	K921114
LPH	MCS/HA	Exactech	K990197

Additionally, the A-Series System is of a similar design to other acetabular components on the market:

<u>Product Code</u>	<u>Model</u>	<u>Manufacturer</u>	<u>510(k) Number</u>
LPH	Reflection	Smith & Nephew	K932755
LPH	Omnifit	Osteonics	-----
LPH	Trilogy	Zimmer	K934765

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Description:

The A-Series acetabular component is a two piece device consisting of a porous metal acetabular shell and a mating polyethylene liner. The metal component is machined from titanium alloy (Ti-6Al-4V) conforming to ASTM F136-96. Three layers of chemically pure titanium beads conforming to ASTM F67-95, grade 2, are sintered to the outer surface of the metal shell to produce the porous coating.

There are three basic shell designs, each of which is available in 14 sizes. Each shell type is available with and without a hydroxyapatite (HA) coating on the beaded surface. The HA coating characteristics are defined in FDA Master File MAF 339 (BioCoat, Inc.).

The acetabular shell design and size options are summarized in Table 1 below.

Metal Acetabular Shell Options			
Design	# Sizes	O.D. Size Range	HA Coating Option?
Screwless (no holes)	14	44 – 70 mm	Yes
Cluster* (3 dome holes)	14	44 – 70 mm	Yes
Multi-Hole* (4 rim holes, 8 dome holes)	14	44 – 70 mm	Yes
*These designs allow for the use of Ti-6Al-4V bone screws to supplement fixation if desired.			

Table 1

The A-Series cups are intended for press-fit applications. Components without the HA coating may also be used in cemented applications. Instrumentation is used to prepare the cavity of the acetabulum for implanting of the shell. The A-Series shells are designed such that an interference condition is created between the prepared acetabulum and the rim diameter of the porous coated shell. Instrumentation is used to impact the shell into the bone for a secure fit. The cluster and multi-hole designs allow for use of Ti-6Al-4V bone screws to supplement fixation if desired.

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The A-Series acetabular liner is composed of ultra-high-molecular-weight polyethylene (UHMWPE) as called out in ASTM F648-98. There are five primary liner designs with various sizes having the ability to accept 22, 26, 28, and 32 mm diameter femoral heads. The minimum bearing thickness for each liner type is greater than 6 mm.

The acetabular liner options are summarized in Table 2.

UHMWPE Liner Design	Sizes	I.D.	Characteristics
15° Liner	7 sizes	22,26 mm	15 ° Face Angle
	6 sizes	28 mm	
	4 sizes	32 mm	
0° Liner	7 sizes	22,26 mm	0° Face Angle
	6 sizes	28 mm	
	4 sizes	32 mm	
Extended Coverage	7 sizes	22,26 mm	5° / 20° Face Angle
	6 sizes	28 mm	
	4 sizes	32 mm	
15° Lateralized + 4 mm	7 sizes	22,26,28,32 mm	Center rotation displaced 4mm laterally.
0° Lateralized + 4 mm	7 sizes	22,26,28,32 mm	Center rotation displaced 4mm laterally.

Table 2

The A-Series has an apical hole locking mechanism and a 12-tab anti-rotational indexing system at the rim of the cup.

Packaging and Sterilization:

A-Series Acetabular components are double packed in thermoformed trays and sealed with Tyvek® lids. The UHMWPE liners are vacuum sealed in two pouches. The bone screw packaging includes two heat sealed pouches (non-vacuum). Inner packaging units are placed in cardboard containers and sealed with shrink wrap. The A-Series packaging also includes various product identification labels, sterility labels, product tracing labels and sterility indicators.

The AcuMatch A-Series is sterilized by gamma irradiation to a Sterility Assurance Level (SAL) of 10⁻⁶. Exactech utilizes Method 3, Protocol B from the "AAMI Guideline for gamma radiation sterilization" for the sterility dose setting and validation procedures.

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Intended Use:

All Exactech Hip Systems 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.

The AcuMatch A-Series Porous Coated Acetabular Components are indicated for 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.

Substantial Equivalence Information:

The Exactech AcuMatch A-Series Porous Coated Acetabular Component has the same intended uses and similar technological features as Exactech's MCS line of acetabular components.

The A-Series and MCS devices have identical material specifications and surface treatments. Both designs consist of a titanium alloy shell (Ti-6Al-4V, ASTM F136-96) shell and a mating ultra-high-molecular-weight-polyethylene (UHMWPE, ASTM F648-98) liner. Both have hemispherical outside geometries and identical surface coatings made of three uniform layers of chemically pure titanium beads. In addition, both devices offer an optional hydroxyapatite (HA) coating for the beaded surface. Detailed surface characterizations, including relevant performance data is found in Exactech's MCS and MCS/HA premarket notifications, #K921114 and #K990197.

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There are more liner and shell options with the A-Series line. While the MCS series offers a multi-hole and a peripheral screw design, the A-Series also includes no-hole, multi-hole and cluster hole configurations. In addition to the standard 0° and standard 15° options of the MCS line, the A-Series components include extended coverage, 0° +4mm lateralized and 15° +4mm lateralized liners.

Both the MCS and A-Series have apical hole locking mechanisms. The anti-rotational indexing system at the rim of the cups differ in that the A-Series has twelve tabs and the MCS is octagonal in configuration. Tests were performed to determine the torsional strength of the proposed A-Series system in comparison to Exactech's MCS cup. The torsional study shows that the locking mechanism on the A-Series is stronger than the same size MCS component. Another engineering evaluation shows that the force required to disengage an A-Series liner from its shell exceeds the force required to disassemble the MCS component. An engineering report modeling the clearance between the spherical radius of the A-Series shell and liner shows a 0.008 inch difference for the least material condition and 0.001 inch difference for the maximum material condition.

In addition to similarities with the Exactech MCS components, the A-Series has a similar geometry, material composition, surface characterization and locking mechanism to other devices legally marketed by other manufacturers. These include but are not limited to the Reflection by Smith and Nephew, the Omnifit by Osteonics, the Trilogy by Zimmer and the Inter-Op by Sulzer. Each of these devices, like the Exactech A-Series, is indicated for press-fit and cemented applications and is supplied sterile. All the predicate devices are made of the same materials as the A-Series, a Ti-6Al-4V alloy shell with a mating UHMWPE liner. These materials have historically proven to be successful in orthopedic implant applications. The Reflection model by Smith and Nephew and the Omnifit model by Osteonics have a titanium beaded porous surface similar to the A-Series. Sulzer's Inter-OP acetabular components have an option for an additional hydroxyapatite (HA) coating as does the Exactech A-Series. All the predicate devices have hemispherical geometries, save the Omnifit which has a dual radius design. The minimum thickness of the polyethylene liner for the A-Series is 6.3 mm compared to a 3.9mm minimum thickness for the MCS. The other predicate devices have minimum liner thicknesses ranging from 5.0 to 7.6 mm.

Lever out torque analysis of the new Exactech A-Series component places the strength of the locking mechanism in the range of other legally marketed devices.



NOV 19 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993082
Trade Name: Exactech Integrated Hip System
Regulatory Class: II
Product Codes: LPH and JDI
Dated: September 14, 1999
Received: September 15, 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 controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

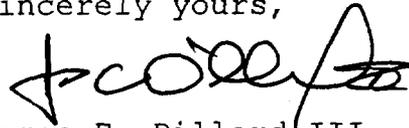
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Lisa Simpson

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is stylized and includes a large, sweeping flourish at the end.

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
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Indications for Use

510(k) Number: K993082

Device Name: Exactech® AcuMatch™ Integrated Hip System
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Indications for Use:

All Exactech Hip Systems 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.

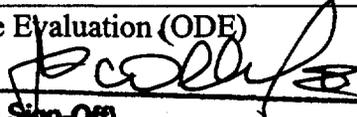
The AcuMatch A-Series Porous Coated Acetabular Components are intended to be used in press fit and cemented applications.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices
510(k) Number K993082

Prescription Use Yes or Over the Counter Use No