FEB 4 [illegible]

K990197

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION FOR THE PREMARKET NOTIFICATION FOR THE MODULUS COMPATIBLE STABILITY (MCS) - HA TOTAL HIP SYSTEM

Exactech, Inc.
Established Registration Number 1038671

The Exactech MCS - HA Porous Coated Total Hip System is made of similar materials and is of a similar design to prostheses that were on the market before May 28, 1976. Additionally, this Porous Coated Total Hip System is of similar design to other components on the market that have been determined to be equivalent to devices on the market prior to May 28, 1976. These predicates include but are not limited to:

1. Exactech **MCS** Total Hip System
2. Charnley
3. Zimmer Harris-Galante
4. Depuy **AML**
5. Osteonics Secur - **Fit HA**
6. Smith & Nephew **Synergy HA**
7. OTI

Material Integrity:
Overall integrity has been previously determined in the initial 510(k) submissions K921113 and K921114. HA coating performance characteristics are further defined in the FDA Master File MAF339 (BioCoat, Inc.) Data obtained meets or exceeds predicate device data. A summary is presented below.

Summary:

The evaluation of the interfacial shear strength of the uncoated sintered bead surface of the Exactech Porous System indicates excellent bonding of the beaded surface to the T1-6A1-4V substrate. Interfacial shear strengths in excess of 27 N/sq.mm can be expected with little variability based on the standard deviations observed for ten coating samples tested.

The integrity of the HA coating has been characterized. The manufacturer acknowledges the importance of coating quality to the success of the device and has collaborated with BioCoat, Inc., a well know coating specialty company, for the application and characterization of its coatings. (Additional information regarding the HA coating has been provided to the FDA as MAF339 by BioCoat)

The HA coating tensile strength on porous coated Ti alloy has been shown to be approximately 55 MPa. The shear strength of the HA on Ti-6Al-4V and Co-Cr-Mo solid

substrates has been shown to be between 5300 and 6500 psi. (36.6-44.8 MPa) while on porous coated Ti-6Al-4V and Co-Cr-Mo substrates the shear strength of the HA is between 5000 and 5900 psi. (34.5-40.7 MPa). Shear fatigue testing of the HA on Ti-6Al-4V shows a fatigue strength of 2000 psi. (13.8 MPa.) at 10 million cycles.

Sterilization

The Exactech HA - MCS Total Hip System will be sterilized by gamma irradiation. The Sterility Assurance Level (SAL) is 10^{-6}. Exactech utilizes Method 3, Protocol B from the "AAMI Guideline for gamma radiation sterilization" for the sterility dose setting and validation procedure.

Utilization and Implantation

Selection of the Exactech HA - MCS Hip System depends on the judgment of the surgeon in relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation by appropriate reading of the literature, and training in the operative skills and techniques required for total hip Arthoplasty surgery.

Indications

The Exactech HA - MCS Total Hip System is indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, osteonecrosis, congenital hip dysplasia, rhematoid arthritis, ankylosing spondylitis and /or posttraumatic degenerative problems. It is also potentially indicated for revision of failed previous reconstruction's where sufficient bone stock is present.

Contraindications

Use of the Exactech HA - MCS Total Hip System is 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 to the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 1999

Gary J. Miller, Ph.D.
Vice President of Research and Development
Exactech®
2320 NW 66th Court
Gainesville, Florida 32653

Re: K990197
Ha Coated MCS Total Hip System
Regulatory Class: II
Product Code: MEH
Dated: January 15, 1999
Received: January 20, 1999

Dear Dr. Miller:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

> You may not label or in any way promote these devices for "enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional porous coated hip prosthesis.

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

"INDICATIONS FOR USE"

510(k) Number (if known) K990197

Device Name:

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. Exactech Hip Systems are also potentially indicated for revision of failed previous reconstruction's where sufficient bone stock is present.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use____

MRC

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990197