DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 1996

William N. Thompson
Director, Quality Assurance and Regulatory Affairs
US Medical Products, Inc.
Suite 100
12201 Technology Boulevard
Austin, Texas 78727

Re: K955386
Consensus® Zirconia Femoral Head
Regulatory Class: II
Product Code: LZO
Dated: November 21, 1995
Received: November 22, 1995

Dear Mr. Thompson:

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 to devices marketed in interstate commerce prior to May 28, 1976 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 and the following limitations:

1. The contraindications of the labeling must include: "The Zirconia Ceramic Head is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup."

2. The Zirconia Ceramic Femoral Heads listed in your document are to be used only with US Medical's hip stems with a 12/14 taper trunnion.

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 (Performance Standards) 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic

GMP 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notifcation. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health