DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 1996

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

Re: K960151
Consensus® 26mm CoCrMo Femoral Head
K960156
Consensus® 32mm CoCrMo Femoral Head
Regulatory Class: II
Product Code: JDI
Dated: January 8, 1996
Received: January 11, 1996

Dear Mr. Thompson:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. 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 devices as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices to proceed to the market, but it does not mean that FDA approves your devices. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice for your devices 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-302) at (301) 594-4639. 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.

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

Enclosure

PREMARKET 510(k) NOTIFICATION FOR

US MEDICAL PRODUCTS, INC.

CONSENSUS® 32mm CoCrMo FEMORAL HEAD

1. **Common/Generic Name:** 32mm CoCrMo femoral head

Trade Name: Consensus® 32mm CoCrMo Femoral Head.

Classification Name: The Food and Drug Administration has classified femoral hip joint prostheses as **Class II** devices under the following classifications:

Prosthesis, Hip, Semi-Constrained Metal/Polymer, classification 21 CFR 888.3350

Device Product Code: The Orthopedics Devices Panel has assigned the following Device Product Code for this type of device:

unclassified

2. **Establishment Address:** US Medical Products, Inc.
12201 Technology Boulevard
Suite 100
Austin, TX 78727

Official Contact: William N. Thompson, Director
Quality Assurance and Regulatory Affairs
US Medical Products, Inc.
12201 Technology Boulevard
Suite 100
Austin, TX 78727
Voice (512) 257-4835
Fax (512) 257-8300

Registration Number: 1645480

Owner/Operator Number: 9004124

3. Performance Standards: To date, no performance standards have been established for this type of device. The device will be manufactured in accordance with Good Manufacturing Practices (GMP) regulations and several material specifications which are presented in Attachment 3.

4. Device Description: The Consensus® 32mm CoCrMo Femoral Head is an implant composed of cobalt chrome molybdenum alloy, ASTM F75-87. It will be available in four neck lengths and will be 32mm in overall diameter, and will be available in 12/14 taper trunnion. A detailed description of the Consensus® 32mm CoCrMo femoral head, including drawings, is presented in Attachment 1, and mechanical test results are presented in Attachment 4.

The Consensus® 32mm CoCrMo femoral head is intended for use as an alternative to the metal ball or the ceramic ball in the Consensus® Total Hip System. It is intended for use in hip replacement applications. The Consensus® 32mm 12/14 taper trunnion CoCrMo femoral head is designed for use with 32mm acetabular insert components, and with size-compatible components of the following Consensus® Total Hip System, which were determined to be substantially equivalent per 510(k) number, as indicated below:

Cobalt Chromium Hip Stem component	K922561	SE 7/21/93
HA/Ti Femoral Stem	K935453	SE 7/18/94
Porous Coated Titanium Femoral Stem	K935193	SE 8/18/94
Nonporous Titanium stem	K933499	SE 5/18/94

Please reference in Attachment 1 and the blueprints in Attachment 4 for the stem taper design description. The 12/14 stem taper is identical in all Consensus® hip stems femoral components described above.

5. Intended Use: The Consensus® 32mm CoCrMo femoral head is intended for use with the Consensus® Total Hip System as an alternative to the 28mm CoCr ball and the alumina ceramic ball, which were determined to be substantially equivalent July 21, 1993, and the zirconia head, determined SE on Nov. 6, 1995. It is a single-use device. The use of the Consensus® 32mm femoral head does not change the indications or contraindications for use of the Consensus® Total Hip System described in K922561, pages 3 and 4. The Consensus® femoral head is indicated for use:

1. for primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and avascular necrosis with a non-acute fracture of the femoral neck.
2. for ostroarthrosis involving femoral and acetabular articular surfaces
3. for avascular osteonecrosis and/or non-union of acute femoral neck fractures.
4. for fracture - dislocation of the hip.
5. for Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

6. **Contraindications:** Contraindications for the Consensus® 32mm CoCrMo femoral head are as follows:

1. Any active or suspected latent infection in or about the hip joint.

2. Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and fixation of the prosthesis.

3. Obesity.

4. Mental or neuromuscular disorders which would create an unacceptable risk of prosthesis instability or complications in postoperative care.

7. **Substantial Equivalence:** The Consensus® 32mm CoCrMo femoral head is substantially equivalent: Exactech 32mm CoCrMo femoral head K862234 SE 08-15-86

The equivalence of the Consensus® 32mm CoCrMo femoral head and the aforementioned predicate device is substantiated by the following attachments:

Attachment 1: A detailed device description including technical drawings and sketches of the Consensus® 32mm CoCrMo femoral head.

Attachment 2: Comparisons listing similarities and differences for the predicate device and other precedent devices.

Attachment 3: Material specification/certification samples of the materials used in the manufacture of the Consensus® 32mm CoCrMo femoral head.

Attachment 4: Consensus® 32mm CoCrMo femoral head performance test protocols and results.

8. **Labeling and Advertising:** Draft labeling for this device is provided in Attachment 5. Promotional materials for this device have not been prepared at this time. However, such materials will include information outlined in Attachment 5, "Advertising Claims", and conform to the basic principles in the "Intended Use", "Contraindications", and "Detail Device Description" section of this submission.

9. **Packaging and Sterilization:** Packaging and sterilization of the Consensus® 32mm CoCrMo femoral head components are described and outlined in Attachment 6, "Packaging and Sterilization".

10. Surgical Technique Outline (Directions for Use): The Consensus® 32mm CoCrMo femoral head is intended for use with the Consensus® Total Hip System as an alternative to the Consensus® CoCrMo metalic femoral Head or the Consensus® ceramic head described in 510(k) premarket notification application K922561. It is a single use device. The use of the Consensus® 32mm CoCrMo femoral head in conjunction with the Consensus® Total Hip System components, as an alternative to the 28mm CoCrMo femoral head or the Ceramic head does not change the Surgical Technique described in Attachment 8 of 510(k) K922561, for the Consensus® Total Hip System, determined SE on 7/21/93.

The Surgical Technique Outline is resubmitted in this 510(k) application for convenience, in Attachment 7.

11. Safety and Effectiveness: Pursuant to the provisions of the Safe Medical Devices Act of 1990, US Medical Products, Inc. includes a Summary of Safety and Effectiveness [510(k) Summary] in Attachment 8.