DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

AUG 18 1994

Mr. Steven I. Whitlock
Director of Product Development
U.S. Medical Products, Inc.
912 Capital of Texas Highway, South
Suite 100
Austin, Texas 78746

Re: K935193
Consensus™ Hip System - Porous
Coated Titanium Femoral Stem
Regulatory Class: II
Product Code: LZO and LPH
Dated: October 25, 1993
Received: October 26, 1993

Dear Mr. Whitlock:

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, 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 data provided for the reclassified Biolox Ball manufactured by Cerasiv (formerly Feldmuhle Aktiengesellschaft). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

The stem is labeled for use only with the Biolox balls having the following Cerasiv Model numbers:

28 mm short neck 38.39.7170.105
28 mm medium neck 38.39.7170.115
28 mm long neck 38.39.7170.125

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 devices 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.

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 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. 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, 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,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PREMARKET 510(K) NOTIFICATION FOR U.S. MEDICAL PRODUCTS, INC. CONSENSUS™ HIP SYSTEM - POROUS COATED TITANIUM FEMORAL STEM

1. **Common/Generic Name:**

Hip replacement prosthesis, femoral component.

Trade Name:

Consensus™ Hip System - *Porous Coated Titanium Femoral Stem.*

Classification Name:

The Food and Drug Administration has classified femoral hip joint prostheses as Class II devices under the following classification:

- Hip joint femoral (hemi-hip) metallic, cemented or uncemented prostheses, under classification 21 CFR 888.3360.

Device Product Code:

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

- Prosthesis, Hip, Hemi-, Femoral, Metal: 87KWL

2. **Establishment Address:**

U.S. Medical Products, Inc.
912 Capital of Texas Highway South
Suite 100
Austin, TX 78746

Official Contact:

Steven I. Whitlock, Director of Product Development

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:**

A detailed description of the Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem*, including drawings and mechanical test results is presented in Attachment 1.

The Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* is intended for use with the Consensus™ Total Hip System as an alternative to the CoCrMo femoral component described in 510(k) premarket notification K922561, "substantial equivalence" determination July 21, 1993. It is a single use device which can be used in both cementless or cement fixation applications. The Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* is designed for use with the following Consensus™ Total Hip System components, which were determined to be substantially equivalent per 510(k) number K922561:

Metal Femoral Head Component - 4 Neck Lengths

*Ceramic Femoral Head Component - 3 Neck Lengths

Uncemented Acetabular Component

Cemented Acetabular Component

Bone Screw

Please reference 510(k) K922561, Attachment 1, Consensus™ Total Hip System, for complete description and drawings of the above components.

*Note: The +3.5 mm (Long) neck Biolox® Ceramic Femoral Head was included for addition to the Consensus™ Hip System in 510(k) premarket notification K933499, submitted on July 19, 1993, for use with the Non-Porous Titanium Femoral Stem. The taper of the Porous Coated Titanium Femoral Stem is identical to the taper on the Non-Porous Titanium Femoral Stem, and thereby will also accept the +3.5 mm long neck Biolox® Ceramic Femoral Head.

5. **Intended Use:**

The Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* is intended for use with the Consensus™ Total Hip System as an alternative to the CoCrMo Femoral Stem described in 510(k) premarket notification application K922561, determined to be substantially equivalent July 21, 1993. It is a single use device, for cementless or cemented applications. The use of the Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* in conjunction with the Consensus™ Total Hip System components, as an alternative to the CoCrMo Femoral Stem does not change the indications or contraindications for use of the Consensus™ Total Hip System described in K922561, pages 3 and 4. For convenience, the "Intended Use" section of 510(k) K922561 has been extracted and presented below.

The Consensus™ Total Hip System is indicated for use as:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post traumatic arthritis and avascular necrosis with a non-acute fracture of the femoral neck.

2. Osteoarthrosis involving femoral and acetabular articular surfaces.

3. Avascular osteonecrosis and/or non-union of acute femoral neck fractures.

4. Fracture - dislocation of the hip.

5. Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

6. **Contraindications:**

Contraindications for the Consensus™ Total Hip System 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™ Hip System, *Porous Coated, Titanium Femoral Stem* is substantially equivalent to the femoral components of the HG MultiLock™ Hip System marketed by Zimmer, and the OPTI-FIX® Hip System marketing by Richards Medical Company.

The equivalence of the Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* and the fore mentioned competitive devices is substantiated by the following attachments:

Attachment 1: A detailed device description including technical drawings, sketches and photographs of the Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem.*

Attachment 2: Competitive comparisons listing similarities and differences and competitive advertisements.

Attachment 3: Material specification/certification samples of the materials used in the manufacture of the Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem.*

Attachment 4: Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* performance test protocols and results.

Attachment 5: Pore morphology and integrity of porous coating to substrate interface.

8. **Labeling and Advertising:**

Draft labeling for this device is provided in Attachment 6. Promotional materials for this device have not been prepared at this time. However, such materials will include information outlined in Attachment 6, "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™ Hip System, *Porous Coated, Titanium Femoral Stem* components are described and outlined in Attachment 7, "Packaging and Sterilization".

11. **Surgical Technique Outline (Directions for Use):**

The Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* is intended for use with the Consensus™ Total Hip System as an alternative to the CoCrMo Femoral Stem described in 510(k) premarket notification application K922561. It is a single use device, for cementless or cement fixation applications. The use of the Consensus™ Hip System, *Porous Coated, Titanium Femoral Stem* in conjunction with the Consensus™ Total Hip System components, as an alternative to the CoCrMo Femoral Stem does not change the Surgical Technique described in Attachment 8 of 510(k) K922561, for the Consensus™ Total Hip System, submitted May 28, 1992.

The Surgical Technique Outline is resubmitted in this 510(k) application for convenience, in Attachment 8.

10. **Safety and Effectiveness:**

Pursuant to the provisions of the Safe Medical Devices Act of 1990, U.S. Medical Products, Inc. includes a Summary of Safety and Effectiveness in Attachment 9.