DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 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: K960302
Consensus® All UHMWPE Acetabular Shell
Regulatory Class: II
Product Code: JDI
Dated: January 19, 1996
Received: January 22, 1996

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 (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 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 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, 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-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

K960302

ATTACHMENT 8

Summary of Safety and Effectiveness
510(k) SUMMARY

APR - 1 1996

US MEDICAL PRODUCTS, INC.
CONSENSUS® Acetabular Shell, All UHMWPE

US Medical Products, Inc.
12201 Technology Blvd.
Suite 100
Austin, Texas 78727

William N. Thompson, Director
Quality Assurance and Regulatory Affairs
Voice (512) 257-4835
Fax (512) 257-8300
Date of Preparation: 15 Dec 1995

Trade Name: Consensus® Acetabular Shell, All UHMWPE

Common Name: Hip replacement prosthesis, Acetabular Shell, All UHMWPE

Classification Name: Class II device, under the following classification:

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

Substantial Equivalence: equivalent Acetabular Shell, All UHMWPE components are as follows:

Howmedica *Acetabular Shell, All UHMWPE K912426 SE 8-21-91*

Device Description: The Consensus® Acetabular Shell, All UHMWPE is intended for use with the Consensus® Total Hip System as an alternative to the the metal acetabular shell and UHMWPE acetabular insert components in the Consensus® Total Hip System. It is a single use device. The Consensus® Acetabular Shell, All UHMWPE is designed for use with size compatible Consensus® Total Hip System components:

Femoral Head, Biolox Ceramic	K922561	SE 07-21-93
Femoral Head, Zirconia	K955386	SE 11/06/95
Femoral Head, CoCrMo	K922561	SE 07-21-93

The 22mm diameter, 26mm diameter, and 28mm Shells are intended to be used with compatible diameter femoral head components.

The Concensus® Acetabular Shell, All UHMWPE will be provided sterile and will be available in fourteen sizes for 22mm heads (42mm to 68mm in 2mm increments), in twelve sizes for 26mm heads (46mm to 68mm in 2mm increments), and in eleven sizes for 28mm heads (48-68mm in 2mm increments). The material will be ultra high molecular weight polyethylene (UHMWPE), ASTM F648.

Intended Use: The CONSENSUS® Acetabular Shell, All UHMWPE is indicated for use in:

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.

Summary of Technological Characteristics: The Consensus® Acetabular Shell, All UHMWPE, is designed to articulate with the various Consensus® Hip femoral head components. The Concensus® Acetabular Shell, All UHMWPE, will be provided sterile and will be available in fourteen sizes for 22mm heads (42mm to 68mm in 2mm increments), in twelve sizes for 26mm heads (46mm to 68mm in 2mm increments), and in eleven sizes for 28mm heads (48-68mm in 2mm increments). The material will be ultra high molecular weight polyethylene (UHMWPE), ASTM F648.

Performance Data: The Consensus® Acetabular Shell, All UHMWPE, device performs with substantial equivalence to predicate devices.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Consensus® Acetabular Shell, All UHMWPE, is substantially equivalent to predicate devices.

Other Necessary Information: None Required