DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 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: K954818
Consensus Posterior Stabilized Knee
Regulatory Class: II
Product Code: JWH
Dated: March 22, 1996
Received: March 25, 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 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 this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial insert available is the nominal 10 sized component, which has a minimum polyethylene thickness under the condyles of 6mm.

2. This device may not be labeled or promoted for non-cemented use.

3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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.

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 at (301) 443-6597.

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

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ATTACHMENT 8

Summary of Safety and Effectiveness

510(k) SUMMARY

US MEDICAL PRODUCTS, INC.
CONSENSUS® Posterior Stabilized Knee System

US Medical Products, Inc.
12201 Technology Boulevard
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 Oct. 1995

Trade Name: Consensus® Posterior Stabilized Knee prosthesis

Common Name: Posterior cruciate ligament sacrificing knee prosthesis; PS Knee

Classification Name: Prosthesis, knee, patello/femorotibial, semi-constrained, cemented, polymer/metal/polymer, under classification 21CFR888.3560.

Substantial Equivalence: equivalent Posterior Stabilized Knee components:

Johnson&Johnson PFC® Modular Knee System, K884796, SE 03-29-89.

Device Description: The Consensus® PS Knee tibial insert component is manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648), and is designed to articulate with the Consensus® PS femoral component. The insert has a spine on the central eminence which engages the crossbar of the PS femoral component. The spine is positioned so that the crossbar of the PS femoral component engages at approximately 65° flexion. The inferior surface of each component employs dovetail grooves for positive interlocking with the Consensus® Primary Knee tibial baseplate. The design is available in three sizes and each size is available in five thicknesses.

The Consensus® PS Femoral component is made of CoCrMo alloy (ASTM F75). Both the outer articulating surface and the inner box geometry of the Consensus® PS femoral component are identical to the respective surfaces of the Consensus® Primary Knee femoral component. Therefore, the PS femoral component contains the same deepened

patella groove as the Consensus® Primary Knee femoral component for increased range of motion, utilizes the same instrumentation as the Consensus® Knee for preparing the distal femur, and employs smooth distal pegs for added Medial/Lateral stability. The Consensus® PS femoral component has a shortened patella groove to accommodate the spine of the Consensus® PS tibial insert. It also contains a stabilizing bar located between the posterior condyles which engages the spine of the Consensus® PS tibial insert at high flexion angles.
The Consensus® Posterior Stabilized Knee System will be provided sterile.

The Consensus® Posterior Stabilized Knee is designed for use with the following Consensus® Total Knee System components:

Consensus® All Poly or metal back Patellar component
Consensus® Porous Titanium Stemmed Tibial Baseplate
Consensus® Nonporous Titanium Stemmed Tibial Baseplate
Consensus® CoCr Stemmed Tibial Baseplate

Intended Use: The Consensus® Posterior Stabilized Knee is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis in the absense of the posterior cruciate ligament.
2. Failed osteotomy or unicompartmental replacements
3. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

Summary of Technological Characteristics: The Consensus® PS Tibial Insert is an asymmetric UHMWPE cruciate-sacrificing tibial component designed to articulate with the Consensus® PS Femoral component, and the Consensus® Primary Knee patellar components. The inferior surface of the tibial component employs dovetail grooves for positive interlocking with the tibial baseplate. The design is available in three sizes and each size is available in five thicknesses. The PS Femoral component is asymmetric, with a shortened patella groove to accommodate the spine of the PS tibial insert, and contains a stabilizing bar located between the posterior condyles which engages the spine of the PS tibial insert. It is available in six sizes.

Performance Data: The device performs with substantial equivalence to predicate devices.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Consensus® PS Knee is substantially equivalent to the predicate device.

Other Necessary Information: None Required