DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 1996

Ms. Mary Ellen Freddo
Director Quality Systems and Regulatory Affairs
U.S. Medical Products, Inc.
12201 Technology Boulevard, Suite 100
Austin, Texas 78727

Re: K952943
Consensus All Poly Tibia
Regulatory Class: II
Product Code: JWH
Dated: January 3, 1996
Received: January 5, 1996

Dear Ms. Freddo:

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). 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 component available is the nominal "10 mm" sized component, which has a minimum polyethylene thickness under the condyles of 7.4 mm.

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, 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,

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

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K952943

**ATTACHMENT 8 amended 17 Oct 1995**

**Summary of Safety and Effectiveness**

# 510(k) SUMMARY

US MEDICAL PRODUCTS, INC.
CONSENSUS® KNEE ALL POLY TIBIA

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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 17 Oct 1995

**Trade Name:** Consensus® All Poly Tibia

**Common Name:** All Poly (UHMWPE) tibial baseplate knee prosthesis

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

**Substantial Equivalence:** equivalent All poly tibia components are as follows:

| | | |
|---|---|---|
| Howmedica Duracon All Plastic Tibial component | K922048 | SE Sep 8, 1992 |
| Intermedics Orthopedics All-Poly Tibia | K923443 | SE 3-31-93 |
| Johnson&Johnson PFC All Plastic Tibia | K910563 | SE 5-23-91 |

**Device Description:** The Consensus® Knee All Poly Tibia component is manufactured from ultra-high molecular weight polyethylene (ASTM F648). It is a symmetric cruciate-retaining tibial component and is designed to articulate with the Consensus® Knee primary femoral component. Therefore, it has articulating surface geometry similar to the Consensus® Knee congruent tibial insert component. The inferior surface of each component employs dovetail grooves for macro-cement interdigitation between the implant and the bone. Each component has two titanium X-Ray markers for post-operative evaluation: one placed vertically in the distal end of the stem, and one placed horizontally in the central anterior aspect of the component. The design is available in six sizes and each size is available in five thicknesses. The minimum thickness of polyethylene under the articulating surface is 7.5mm for all sizes. The Consensus® All Poly Tibia will be provided sterile.

The Consensus® All Poly Tibia is designed for use with the following Consensus® Total Knee System components:

Consensus® Nonporous CoCr Femoral component
Consensus® Porous CoCr Femoral Component
Consensus® Patellar component, All Polyethylene
Consensus® Patellar component, Titanium/Polyethylene

**Intended Use:** The Consensus® All Poly Tibia is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
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® All Poly Tibia is a symmetric UHMWPE cruciate-retaining tibial component designed to articulate with the Consensus® Knee primary femoral component. The inferior surface employs dovetail grooves for macro cement interdigitation. Each component has two titanium X-Ray markers, and is available in six sizes, each in five thicknesses, minimum 7.5mm articulating surface thickness.

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

**Clinical Data:** None Required

**Conclusions from Non-clinical and Clinical Data:** The Consensus® All Poly Tibia is substantially equivalent to predicate devices.

**Other Necessary Information:** None Required