DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

SEP 27 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: K932837
Consensus Knee™ System - Primary Knee
Regulatory Class: II
Product Code: JWH
Dated: September 8, 1994
Received: September 9, 1994

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

2. 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.

3. 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 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. 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 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 KNEE™ SYSTEM - PRIMARY KNEE

1. **Common/Generic Name:**

Total knee replacement prosthesis.

Trade Name:

Consensus Knee™ System - Primary Knee.

Classification Name:

The FDA has classified total knee prosthesis as Class II devices under the following classification:

- Classification Number: Orthopedics/87JWH
- Prosthesis, knee, patello/femorotibial, semi-constrained, cemented, polymer/metal/polymer, under classification 21 CFR 888.3560.

2. **Establishment Address:**

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

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 a number of material specifications (see Attachment 3).

4. **Device Description:**

A detailed description of each component of the Consensus Knee™ System - Primary Knee, including drawings is provided in Attachment 1. Briefly, the Consensus Knee™ System consists of the following components:

Non-Porous Femoral Knee Component

The non-porous femoral knee component will be available in a left and right configuration and is designed to replicate the natural anatomy of the femur, incorporating a swept back articular radius on the condyles and a deepened trochlear groove. The femoral component will be made from a cast CoCrMo alloy material. The inner box geometry of the femoral component is designed to minimize bone resection, and incorporates a peg on each condyle to provide medial-lateral stability. The surfaces of the inner box geometry of the nonporous femoral component incorporate recessed pockets to provide cement fixation. The femoral knee component will be available in six (6) sizes to fit the majority of patients encountered.

Porous Femoral Knee Component

The porous femoral knee component will be available in a left and right configuration and is designed to replicate the natural anatomy of the femur, incorporating a swept back articular radius on the condyles and a deepened trochlear groove. The femoral component will be made from a cast CoCrMo alloy material. The inner box geometry of the femoral component is designed to minimize bone resection, and incorporates a peg on each condyle to provide medial-lateral stability. The surfaces of the inner box geometry of the porous femoral component will be porous coated with CoCr beads to provide enhanced cement fixation. The femoral knee component will be available in six (6) sizes to fit the majority of patients encountered.

Non-Porous Stemmed Tibial Component

The non-porous metal backed stemmed tibial component will be available in a left and right configuration and is designed to replicate the natural anatomy of the tibia, incorporating an asymmetrical shape to provide more coverage of the resected tibia. The cruciate shaped smooth stem located on the inferior surface of the component will provide anterior-posterior, medial-lateral and rotational stability. The stem is anatomically positioned, offset medial and anterior from center, and incorporates a radiused contour on the posterior edges, to avoid impingement with the lateral and posterior cortical bone. The metal backing of the tibial component will also have four (4) smooth pegs on the inferior surface to provide enhanced fixation and additional stability. The metal backing of the tibial component will have two (2) strategically placed spherically radiused recessed holes to accept optional bone screws to augment initial fixation. The inferior surface of the non-porous metal backed stemmed tibia will incorporate recessed pockets to provide cement fixation. The polyethylene insert, which snaps onto the metal backing of the tibial component, will be available in a left and right configuration and is designed to incorporate a congruent articular surface, with radii that match the femoral component and also provide for some translation and rotation of the femur that occurs in the knee. The tibial insert and metal backing will have a posterior cutout to allow for a posterior cruciate ligament sparing surgical procedure. The material of the stemmed tibial component will be cast Ti 6Al-4V alloy for the metal backing, and Ultra High Molecular Weight Polyethylene (UHMWPE) for the tibial insert. The stemmed tibial component will be available in six (6) sizes and five (5) thicknesses for each size, to fit the majority of patients encountered.

Porous Stemmed Tibial Component

The porous metal backed stemmed tibial component will be available in a left and right configuration and is designed to replicate the natural anatomy of the tibia, incorporating an asymmetrical shape to provide more coverage of the resected tibia. The cruciate shaped smooth stem located on the inferior surface of the component will provide anterior-posterior, medial-lateral and rotational stability. The stem is anatomically positioned, offset medial and anterior from center, and incorporates a radiused contour on the posterior edges, to avoid impingement with the lateral and posterior cortical bone.

The metal backing of the tibial component will also have four (4) smooth pegs on the inferior surface to provide enhanced fixation and additional stability. The metal backing of the tibial component will have two (2) strategically placed spherically radiused recessed holes to accept optional bone screws to augment initial fixation. The inferior surface of the porous metal backed stemmed tibia will be porous coated with commercially pure titanium beads to provide enhanced cement fixation. The polyethylene insert, which snaps onto the metal backing of the tibial component, will be available in a left and right configuration and is designed to incorporate a congruent articular surface, with radii that match the femoral component and also provide for some translation and rotation of the femur that occurs in the knee. The tibial insert and metal backing will have a posterior cutout to allow for a posterior cruciate ligament sparing surgical procedure. The material of the stemmed tibial component will be cast Ti 6Al-4V alloy for the metal backing, and UHMWPE for the tibial insert. The stemmed tibial component will be available in six (6) sizes and five (5) thicknesses for each size, to fit the majority of patients encountered.

Metal Backed Resurfacing Tibial Component

The metal backed resurfacing tibial component will be available in a left and right configuration and is designed to replicate the natural anatomy of the tibia, incorporating an asymmetrical shape to provide more coverage of the resected tibia. The metal backed tibial component will have four (4) smooth pegs on the inferior surface to provide anterior-posterior, medial-lateral and rotational stability, along with enhanced fixation. The metal backing will also have two (2) strategically placed spherically radiused recessed holes to accept optional bone screws to augment initial fixation. The inferior surface of the metal backed resurfacing component is porous coated with commercially pure titanium beads to provide enhanced cement fixation. The polyethylene insert, which snaps onto the metal backing of the tibial component, will be available in a left and right configuration and is designed to incorporate a congruent articular surface, with radii that match the femoral component and also provide for some translation and rotation of the femur that occurs in the knee. The tibial insert and metal backing will have a posterior cutout to allow for a posterior cruciate ligament sparing surgical procedure. The material of the resurfacing tibial component will be wrought Ti 6Al-4V alloy for the metal backing and UHMWPE for

the tibial insert. The resurfacing tibial component will be available in six (6) sizes and five (5) thicknesses for each size to fit the majority of patients encountered.

All-Polyethylene Patellar Component

The all-polyethylene patellar component is designed to fit either the left or right patella. The patellar component will be an oval configuration to provide more coverage of the resected patella bone. The articular surface of the patella will be an offset spherical dome. The bone interface side of the patella will have three (3) pegs and recessed pockets to provide cement fixation. The material of the all-polyethylene patella will be UHMWPE. The patella will be available in three (3) sizes to fit the majority of patients encountered.

Metal Backed Patellar Component

The metal backed patellar component is designed to fit either the left or right patella. The patella component will be an oval configuration to provide more coverage of the resected patella bone. The articular surface of the patella will be an offset spherical dome. The bone interface side of the patella will be porous coated with commercially pure titanium beads to provide enhanced cement fixation of the component. The design also incorporates three (3) pegs to provide stability and enhance fixation. The material of the metal backed patellar component will be wrought Titanium 6Al-4V alloy for the metal backing and UHMWPE for the domed articular component. The domed articular component and the metal backing are preassembled by the manufacturer. The patella will be available in three (3) sizes to fit the majority of patients encountered.

A detailed description of each component is provided in Attachment 1, "Detail Device Description", of Section 7, "Substantial Equivalence".

5. **Intended Use:**

The Consensus Knee™ System - Primary Knee is designed as a system and is not intended for substitution of components from other systems. This device is intended for cemented use only. The indications for use are:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post traumatic arthritis or degenerative arthritis.

2. Failed osteotomies or unicompartmental replacements.

3. Replacement of unsatisfactory cemented or press fit knee components if sufficient bone stock exist.

6. **Contraindications:**

Contraindications for the Consensus Knee™ System - Primary Knee are as follows:

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

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

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

4. Conditions that tend to place increased loads on implants such as age, weight and activity level which are incompatible with a satisfactory clinical long-term result.

7. **Substantial Equivalence:**

Femoral Knee Component

The Consensus Knee™ System non-porous and porous femoral component is substantially equivalent to the Natural-Knee® System femoral component marketed by Intermedics Orthopedics, and the Genesis™ Total Knee System femoral component marketed by Smith & Nephew Richards.

Metal Backed Stemmed Tibial Component

The Consensus Knee™ System non-porous and porous stemmed tibial component is substantially equivalent to the Natural Knee® System stemmed tibial component marketed by Intermedics Orthopedics, and the Genesis™ Total Knee System stemmed tibial component marketed by Smith & Nephew Richards.

Metal Backed Resurfacing Tibial Component

The Consensus Knee™ System resurfacing component is substantially equivalent to the Natural Knee® System resurfacing component marketed by Intermedics Orthopedics.

Patellae Components

The Consensus Knee™ System all-poly patella and metal backed patella components are substantially equivalent to the Natural Knee® system all-poly patella and metal backed patella components marketed by Intermedics Orthopedics, and the Genesis™ Total Knee System all-poly patella and metal backed patella components marketed by Smith & Nephew Richards.

The equivalence of the Consensus Knee™ System and the above mentioned competitive devices is substantiated by the following attachments:

Attachment 1	A detailed device description including technical drawings, sketches and photographs of the system components.
Attachment 2	Competitive comparisons listing similarities and differences and competitive advertisements.
Attachment 3	Material specifications/certification samples of the materials used in the manufacture of the system components.
Attachment 4	Component performance test protocols and results/discussions.
Attachment 5	Pore morphology and integrity of porous coating/substrate interface.

8. **Labeling and Advertising:**

Draft labeling for this device is provided in Attachment 6, "Draft Labeling and Advertising Claims". Promotional materials for this device have not been prepared at this time. However, such materials will include information outlined in Attachment 6, and conform to the basic principles in the "Intended Use", "Contraindications" and "Detail Device Description" sections of this submission.

9. **Packaging and Sterilization:**

Packaging and sterilization of the Consensus Knee™ System - Primary Knee components are described and outlined in Attachment 7, "Packaging and Sterilization".

10. **Safety and Effectiveness:**

Pursuant to the provisions of the Safe Medical Devices Act of 1990, we will make information respecting safety and effectiveness available upon request by any person.

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

The Consensus Knee™ System - Primary Knee Surgical Technique is outlined in Attachment 8, "Surgical Technique Outline".

In conclusion, U.S. Medical Products, Inc. believes that based on the device descriptions, intended use, contraindications, labeling and advertising claims, packaging and sterility, materials, performance test results and the tabulated competitive comparisons found in Tables 1-5 of Attachment 2, our devices are substantially equivalent to other pre- and post-enactment devices currently on the market.