DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1996

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

Re: K962215
Trade Name: Consensus® Posterior Stabilized Knee-Intercondylar Notch Router
Regulatory Class: I
Product Code: HWE
Dated: May 28, 1996
Received: June 10, 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). 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.

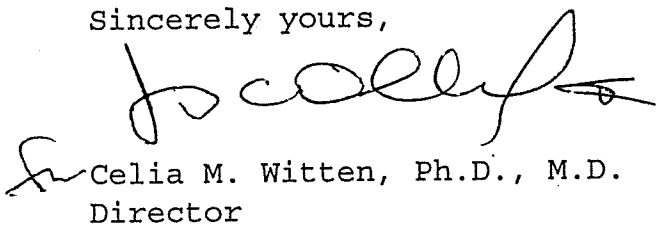
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, 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) 594-4595. 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

Enclosure

AUG 1 5 1996

K962215

ATTACHMENT VII

Summary of Safety and Effectiveness
510(k) SUMMARY
Consensus® Posterior Stabilized Knee-
Intercondylar Notch Router

US MEDICAL PRODUCTS®, INC.

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

Mary Ellen Freddo
Director, Quality Systems and Regulatory Affairs
Voice (512) 257-4835
Fax (512) 257-8300
Date of Preparation: Tuesday, May 28, 1996

Trade Name: Consensus® Posterior Stabilized Knee-Intercondylar Notch Router

Common Name: Intercondylar Notch Router

Classification Name:

Substantial Equivalence:

Whiteside ORTHOLOC II Posterior Stabilized End Mill and Template

Intermedics Orthopedics® Natural Knee II System Posterior Stabilized Router Assembly

Device Description: A template is placed on the distal femur. This template is made from stainless steel (17-4PH SS @ H900). The template contains a central groove with adequate markings that ensure proper guidance of the router.

The router itself consists of a router bit (17-4PH SS @ H900), the shank of which is encased in a plastic body (Ultem® 4000) that acts as a handle for the surgeon and as a journal bearing for the shaft of the router bit.

The base of the body has a large diametrical flange that rests on the superior surface of the template. This flange acts to stabilize the router against torsional forces created by the router bit. The superior end of the router shank is attached to a standard flexible shaft. A standard Zimmer fitting is integrally machined to the superior side of the flexible shaft in order to accommodate a standard operating room power drill (Stryker, 3M, etc.).

The router body and bit are available in one size. The template is available in three sizes; size 1/2, size 3/4, and size 5/6. This accommodates the range of Consensus® Knee posterior stabilized femoral components.

Intended Use: The Consensus® Posterior Stabilized Knee system employs a router device to remove the intercondylar bone from the distal portion of the femur. This bone must be removed to accommodate the spine of the posterior stabilized tibial insert. This procedure occurs after all bone resections of the distal femur have been completed in the traditional manner with the existing Consensus® Knee instruments.

Summary of Technological Characteristics:

Summary of Risk Analysis: The risk analysis showed that none of the possible failure modes resulted in a risk index greater than 10. According to the scale, no additional action is required to address risk and/or hazards resulting from the use of this device. Preventative measures that are incorporated into the design are shown on the risk analysis of Section ___

Performance Data: No performance data exists for this device.

Clinical Data:	None Required
Conclusions from Non-clinical and Clinical Data:	None Required
Other Necessary Information:	None Required