DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1995

Mr. William N. Thompson
Director
Quality Assurance and Regulatory Affairs
U.S. Medical Products, Inc.
912 Capitol of Texas Highway, Suite 100
Austin, Texas 78746

Re: K945589
Consensus™ Knee Cobalt Chrome
Non-porous Stemmed Tibial Baseplate
Dated: November 7, 1994
Received: November 14, 1994

Dear Mr. Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine whether the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require additional information.

1. Provide complete, dimensioned engineering drawings of the submitted device and all unique instrumentation required for implantation of the submitted device.

2. Provide the catalog numbers for all submitted device sizes.

3. Modify the package label to include the "Cemented Use Only" warning.

4. Make the following changes to the package insert:

   a. modify the device description to include the submitted device;

   b. Either remove all references to resterilization of the device from the package insert or state that the following steps will be performed prior to marketing:

      (1) identify a recommended set or sets of sterilization process parameters (for steam - the cycle, temperature, and exposure time;

(2) validate that each recommended set of sterilization process parameters will obtain a resulting SAL of 10^{-6}; and

(3) identify the sterility validation method that will be or was used.

5. Provide the following information in support of the fatigue test report contained in Attachment 4:

a. complete, dimensioned engineering drawings of the tested Ti alloy component; and

b. confirmation that the data contained in the test report were generated by following the provided test protocol, TP-0007. From the presentation of the data in the test report, it appears that a different test protocol may have been followed.

6. State whether the submitted device will be manufactured from materials corresponding to ASTM F75 or ASTM F799 and correct the package insert and Summary of Safety and Effectiveness accordingly.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If the information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Mr. Aric D. Kaiser at (301) 594-2036. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Stephen P. Rhodes

for Ann C. Tornese
Acting Deputy Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health