DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

JAN 27 1995

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

Re: K945186
Consensus™ Acetabular Reamer
K945208
Consensus® Hip Stem - Trochanteric Cutter
Regulatory Class: I
Product Code: HWE and KIJ
Dated: October 20, 1994
Received: October 24 and 25, 1994

Dear Mr. Thompson:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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). You may, therefore, market the devices, 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 practices, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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 immediately will allow you to begin marketing your devices as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices to proceed to the market, but it does not mean that FDA approves your devices. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice regarding labeling for your devices in accordance with 21 CFR Part 801, 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 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