DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2000

Mr. William J. Griffin
QS&RA Manager
Hayes Medical, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762

Re: K001456
Trade Name: Tibial Baseplate, Cast, CorCr/Ti Porous and CoCr Non-Porous
Regulatory Class: II
Product Code: JWH
Dated: May 5, 2000
Received: May 9, 2000

Dear Mr. Griffin:

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 control provisions of the Act. The general control 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4659. 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachman.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8
Statement of Indications for Use K001456

The *Consensus*® Knee System and the CoCr/Ti porous or CoCr nonporous tibial baseplate is design for use as a system, and is not intended for substitution with components of 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 osteotomy or unicompartmental replacements.
3. Replacement of unsatisfactory cemented or press fit knee components, if sufficient bone stock exists.

Contraindications for use of the device are:

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.

Donna R. Lochner

(Division S... ...)
Division of ... Restorative Devices
510(k) Number: K001456