DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2002

Mr. William J. Griffin
QS&RA Manager
Hayes Medical, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, CA 95762-9623

Re: K020153
Trade Name: Acetabular Shell, Porous Ti TI Coating
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: January 14, 2002
Received: January 16, 2002

Dear Mr. Griffin:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

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

The Ti coated porous acetabular shell is design for use with the *Consensus*® or *UniSyn* ® Hip Systems, and is not intended for substitution with components of other systems. The device is intended primarily for uncemented, press-fit applications. The indications for use are:

With Consensus® System:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post traumatic arthritis or degenerative arthritis, and avascular necrosis with a non-acute fracture of the femoral neck.
2. Osteoarthrosis involving femoral and acetabular articular surfaces.
3. Avascular osteonecrosis and/or non-union of acute femoral neck fractures.
4. Fracture or dislocation of the hip.
5. Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

With UniSyn ® System:

1. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
2. Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
3. Proximal femoral fractures.
4. Avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.
7. Indications for the use of the UniSyn Hip System must be carefully considered with respect to the patient's entire evaluation and alternative procedures. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding activity and joint loading are assured. This includes all patients who may or may not have multiple joint involvement, for whom restoration of joint mobility leads to an expectation of greater mobility and an improvement in the quality of life.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020153