NOV 25 1998

K983004

HAYES MEDICAL, INC.
***Consensus*® Knee System**
CoCr/Ti Femoral Component

510(k) Premarket Notification

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, and Contact Person

Hayes Medical, Inc.
819 Striker Ave., Suite 10
Sacramento, CA 95834
Telephone: (916) 646-5431
Facsimile: (916) 646-5432

Contact Person: John B. Stassi
Director, Compliance

Date Prepared: August 15, 1998

Name of Device and Name/Address of Sponsor

Trade name: *Consensus*® Femoral Component, Porous, CoCr/Ti

Hayes Medical, Inc.
819 Striker Ave., Suite 10
Sacramento, CA 95834

Classification Name

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 C.F.R. § 888.3560)

Predicate Devices

1. *Consensus*®, Knee System Femoral Component, Porous, CoCr, marketed by Hayes Medical, Inc. (K932837)
2. The Natural-Knee® femoral component marketed by Sulzermedica, Inc.
3. The Genesis™ Total Knee System marketed by Smith & Nephew Richards, Corp.

Intended Use

The *Consensus*® CoCr/Ti Femoral Component is intended for use with the *Consensus*® Knee System and is not intended for substitution of components from other systems. *This device is intended for cemented use only.* The indications for use are as follows:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis;
2. Intervention of failed osteotomies and unicompartmental replacements;
3. Replacement of unsatisfactory cemented or press fit knee components if sufficient bone stock exists.

Device Description

The porous femoral knee component will be available in a left and right configuration and is designed to replicate the natural anatomy of the femur. The design of the femoral component incorporates a swept-back radius on the outer condyle surfaces to allow for smooth articulation throughout the range of motion[2]. The outer articular surface of the femoral component will also have a deepened trochlear groove to allow for more anatomic tracking of the patellar component and improved range of motion. The material will be cast CoCrMo alloy (ASTM F75-92). The inner box geometry of the femoral component is designed to allow a minimum bone resection of 10mm distal, 9mm posterior, and 6.5mm anterior. The anterior flange of the femoral component is angled 4°outward, posterior to anterior, to reduce the potential for notching the anterior femur. The anterior flange will also

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[2] Mensch, et al.; Knee Morphology as a Guide to Knee Replacement, *Clinical Orthopaedics and Related Research*, No. 112, October 1975.

incorporate a stepped chamfer which allows for positioning the trochlear groove in a more anatomic position. A smooth tapered peg will be located on each distal condyle to provide medial-lateral stability and enhanced fixation. The surfaces of the inner box geometry of the porous femoral component will incorporate a sintered porous coating of CoCr beads (ASTM F75-92), which will subsequently be coated with Titanium alloy (ASTM F67-95). The porous coating is designed to enhance cement fixation.

Summary Basis for Finding of Substantial Equivalence

The *Consensus*® CoCr/Ti Femoral Component has substantially the same intended use and indications for use as the predicates as well as similar performance and principles of operation. The technological differences between the *Consensus*® CoCr/Ti Femoral Component and the predicate devices have been thoroughly documented and tested in order to verify that no new issues of safety and effectiveness are raised by the design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Mr. John Stassi
Director, Compliance
Hayes Medical, Inc.
819 Striker Avenue, Suite 10
Sacramento, California 95834

Re: K983004
Consensus® Knee System Femoral Component, Porous, CoCr/Ti
Regulatory Class: II
Product Code: JWH
Dated: August 20, 1998
Received: August 28, 1998

Dear Mr. Stassi:

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

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 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

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

510(k) Number (if known): K983004

Device Name: *Consensus*® Femoral Component, Porous, CoCr/Ti

Indications For Use:

The *Consensus*® CoCr/Ti Femoral Component is intended for use with the *Consensus*® Knee System and is not intended for substitution of components from other systems. *This device is intended for cemented use only.* The indications for use are as follows:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis;
2. Intervention of failed osteotomies and unicompartmental replacements;
3. Replacement of unsatisfactory cemented or press fit knee components if sufficient bone stock exist.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983004