K060635

Section 9
510(k) Summary of Safety and Effectiveness

Defined in 21 CFR 807
In accordance with 21 CFR 807.92 (Summary)

APR 28 2006

Applicant's Name:	Hayes Medical, Inc. 1115 Windfield Way, Suite 100 El Dorado Hills, CA 95682
Contact Person:	Luke Rose
Trade Name:	Consensus Acetabular Shell System
Common Name:	Acetabular Shell, porous, uncemented
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358, Product Code LPH) Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Product Code LZO)
Proposed Regulatory Class:	Class II
Device Classification Panel:	Orthopaedic
Substantially Equivalent To:	Hayes Medical, *Consensus Acetabular Shell* (K922561) Wright Medical, *Lineage Cup* (K002149) Apex Surgical, *Modular Acetabular Cup* (K031110) Orthopaedic Source, *Avalon Acetabular Cup* (K022711) Encore, *Foundation Porous Acetabular System* (K974095)

Intended Use:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- Proximal femoral fractures
- Avascular necrosis of the femoral head
- Non-union of proximal femoral neck fractures
- Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion and structural abnormalities.

Device Description:

The Consensus Acetabular Shell System consists of four modular shell options which mate with currently marketed polyethelyne insert components for replacement of the acetabular surface during total hip arthroplasty. The shells are designed to be implanted without bone cement. Cementless (press-fit) fixation is achieved by coating the external surface of the cup with commercially pure (CP) titanium sintered beads.

All of the shell options have the following common features:

- The substrate material of the Consensus Shells is titanium alloy (ASTM F136, Ti-6Al-4V)

- The shell is porous coated with commercially pure (CP) titanium sintered beads (ASTM F67, irregular bead geometry).
- The shells have the same internal locking mechanism as the previously cleared Consensus Acetabular Shells (K922561).
- The apical dome hole of the shells is threaded to accept an impaction tool for implanting the component. After implantation and the impaction tool is removed, a threaded titanium (ASTM F67 or F136) hole plug can be inserted into the threaded hole to prevent migration of unwanted particles through the dome hole.

The following shell options are available:

- Total Hemispherical in no screw holes or three (3) quadrant screw holes options.
- Hemispherical with rim flare in no screw holes or three (3) quadrant screw holes options.

Comparison to Cleared Device

The following changes have been made to the previously cleared Consensus Acetabular Shell (K922561):

- Addition of the Hemisphical with rim flare outer profile
- Removal of the two inferior screw holes. Holed cups now have three instead of five screw holes.
- The apical dome hole has been threaded.
- A threaded apical dome hole plug is now available.
- The porous coating is being modified from a spherical sintered CP titanium bead to an irregular sintered CP titanium bead.

The locking mechanism between the polyethylene (UHMWPE) liner and the acetabular shell is identical to the previously cleared Consensus Acetabular Shell (K922561). The safety and effectiveness of this locking detail is described in testing contained within the original submission.

Substantial Equivalence Information

The intended use, material, design features and type of interface of the Consensus Acetabular Shell System are substantially equivalent to competitive devices previously cleared for market. The safety and effectiveness of the Consensus Acetabular Shell System are adequately supported by the substantial equivalence information and materials data provided within this Special 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Hayes Medical, Inc.
c/o Mr. Luke Rose
Director, Quality Systems and Regulatory Affairs
1115 Windfield Way - Suite 100
El Dorado Hills, California 95762

Re: K060635
Trade/Device Name: Consensus Total Hip System, Acetabular Cup
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: LPH and LZO
Dated: March 30, 2006
Received: March 31, 2006

Dear Mr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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.

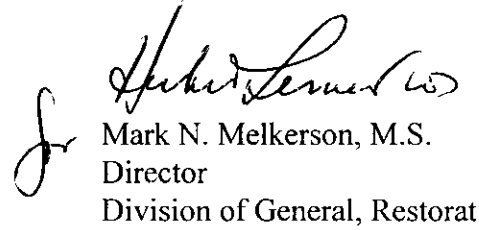
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K06-0635

Device Name: Consensus Acetabular Cup System

Indications For Use:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C. Proximal femoral fractures
D. Avascular necrosis of the femoral head
E. Non-union of proximal femoral neck fractures
F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion and structural abnormalities.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060635