K070061 Pg 1 of 2

Special 510(k)
Consensus Hip System – Addition of a 36mm CoCrMo Femoral Head and Acetabular Insert

Revised Section 9
510(k) Summary of Safety and Effectiveness

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

JAN 3 1 2007

Applicant's Name:	Hayes Medical, Inc. 1115 Windfield Way, Suite 100 El Dorado Hills, CA 95682
Contact Person:	Luke Rose
Trade Name:	36mm femoral head, Consensus Hip
Common Name:	36mm femoral head, Consensus Hip
Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR 888.3360, LWJ) Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350, JDI) Hip System acetabular Insert (21 CFR 888.3358, LPH
Proposed Regulatory Class:	Class II
Device Classification Panel:	Orthopaedic
Substantially Equivalent To:	Hayes Medical Consensus Hip System (K922561) Hayes Medical Crosslinked UHMWPE Insert (K021466) DePuy 36mm UHMWPE highly crosslinked liner (K994415) Biomet Orthopedics, Inc., RingLoc® 36mm femoral head and liner (K032396)

Intended Use:

Indications for use of the Consensus™ Hip System or UNISYN™ Hip System

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

Acetabular components are indicated for cemented and cementless use.
Consensus femoral stems are indicated for cemented and cementless use.
UniSyn femoral stems are indicated for cementless use only.
HA coated implants are indicated for cementless use only.

Device Description:

The Consensus Hip 36mm CoCrMo (ASTM F799 or ASTM F1537) femoral head is offered with four different offsets, -5mm, neutral, +5mm and +10mm. Other than size, it incorporates no new design features. Female head taper is identical to the head taper design for the cleared devices.

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Special 510(k)
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The 36mm acetabular insert is offered in sizes 54 – 68 (2 mm increments), in neutral, 10 and 20 degree hooded configurations. Material for all 36mm insert sizes is crosslink UHMWPE (ASTM F648). Hooded configurations incorporate a titanium alloy x-ray marker (Ti 6Al-4V ELI ASTM F136). Insert locking detail of the subject device is identical to the locking detail of the cleared devices.

Comparison to Cleared Device:

The only change made to the previously cleared Consensus femoral heads and liners is the addition of a new size, the 36 mm femoral head and a series of compatible acetabular inserts, including 10 and 20 degree hooded configurations.

Substantial Equivalence Information

The intended use, material, design features and type of interface of the 36mm femoral head and inserts are substantially equivalent to predicate Hayes Medical and competitive devices. The safety and effectiveness of the subject 36mmm head and inserts 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

Hayes Medical, Inc.
% Mr. Luke Rose
Director, Quality Systems
and Regulatory Affairs
115 Windfield Way, Suite 100
El Dorado Hills, California 95762-9623

JAN 31 2007

Re: K070061
Trade/Device Name: Consensus Hip System 36 mm CoCr Femoral Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Regulatory Class: II
Product Code: JDI, LWJ, LPH
Dated: January 4, 2007
Received: January 5, 2007

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.

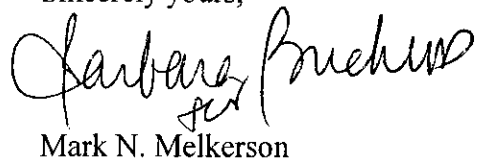
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Special 510(k)
Consensus Hip System – Addition of a 36mm CoCrMo Femoral Head and Acetabular Insert

Revised Section 7
Indications for Use

510(k) Number (if known): K070061

Device Name: Consensus Hip System

Indications For Use:

Indications for use with the CONSENSUS® Hip System or UNISYN™ Hip Ssytem

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

Acetabular components are indicated for cemented and cementless use.
Consensus femoral stems are indicated for cemented and cementless use.
UniSyn femoral stems are indicated for cementless use only.
HA coated implants are indicated for cementless use only.

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)

Barbara Boneburg

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

510(k) Number K070061