K062383 - Third Revised Section 9
510(k) Summary of Safety and Effectiveness

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

DEC 2 1 2006

Applicant's Name:	Hayes Medical, Inc. 1115 Windfield Way, Suite 100 El Dorado Hills, CA 95682
Contact Person:	Luke Rose
Trade Name:	Body, UniSyn Modular Hip
Common Name:	Body, HA Plasma, Modular 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) Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353, LZO) Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate (21 CFR 888.3353, MEH)
Proposed Regulatory Class:	Class II
Device Classification Panel:	Orthopaedic
Substantially Equivalent To:	Hayes Medical Unisyn Modular Hip System (K003649) Hayes Medical HA Coated Consensus Hip System (K935453) Howmedica/Osteonics, *Restoration Modular System* (K022549) Biomet Orthopedics, Inc., *HA Modular Reach Proximal Porous* (K022463)

Intended Use:

Indications for use of the UNISYN™ HIP SYSTEM
A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
B) Revision of failed femoral head replacement, hip 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, pseudarthrosis conversion, and structural abnormalities.

Device Description:

The Body, HA Plasma, Modular Hip is part of the Unisyn modular hip system. The system consists of three parts; the neck, the body, and the stem. There are thirty-three different proximal bodies with six different cone diameters with multiple medial projections for each size. There are also cone-only bodies with and without collars. The surface of the body is plasma sprayed with a secondary coating of hydroxylapatite.

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Comparison to Cleared Device:

The only change made to the previously cleared UniSyn Hip System (K003649) is the addition of hydroxylapatite coating to the existing TPS coating on the surface of the bodies.

Substantial Equivalence Information

The intended use, material, design features and type of interface of the Body, HA Plasma, Modular Hip are substantially equivalent to Hayes Medical and competitive devices previously cleared for market. The safety and effectiveness of the Body, HA Plasma, Modular Hip are adequately supported by the substantial equivalence information and materials data provided within this Special 510(k) submission.

510(K) ROUTE SLIP
SPECIAL

JNG

510(k) NUMBER: K062383 PANEL: OR DIVISION: DGRND BRANCH: OJDB

ELECTRONIC SUBMISSION: N

TRADE NAME: UNISYN HA PLASMA MODULAR HIP

COMMON NAME: BODY, HA PLASMA, MODULAR HIP

PRODUCT CODE: LWJPROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, UNCE

APPLICANT: HAYES MEDICAL, INC.
SHORT NAME: HAYEMEDI
CONTACT: LUKE ROSE
DIVISION:
ADDRESS: 1115 WINDFIELD WAY, SUITE 100
EL DORADO HILLS, CA 957629623
PHONE NO. (916) 355-7156 FAX NO. (916) 355-7190

MANUFACTURER:	REG NO.
HAYES MEDICAL, INC.	2952369
STERITEC, INC.	1647149
BIO-COAT, LLC	1833658

DATE ON SUBMISSION: 10-AUG-2006 DATE DUE POS: 09-SEP-2006

DATE RECEIVED IN ODE: 15-AUG-2006 DATE DECISION DUE: 14-SEP-2006

DECISION: __ DECISION DATE: _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	25-SEP-2006	27-SEP-2006	22-OCT-2006	27-OCT-2006	24-OCT-2006
S002	11-DEC-2006	12-DEC-2006	06-JAN-2007	11-JAN-2007	

CORRESPONDENCE	SENT	DUE BACK	
C001	06-SEP-2006	06-OCT-2006	HOLD LETTER
C002	24-OCT-2006	22-DEC-2006	HOLD LETTER

Is this 510(k) identified as a Class III device ____YES ____NO
Is this 510(k) the result of additional information ____YES ____NO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hayes Medical, Inc.
% Dr. Luke Rose
Director, QS&RA
1115 Windfield Way
Suite 100
El Dorado Hills, California 95762

DEC 21 2006

Re: K062383
Trade/Device Name: UniSyn Modular Hip System
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: LWJ, LZO, JDI, MEH
Dated: December 11, 2006
Received: December 12, 2006

Dear Dr. 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

Indications for Use

510(k) Number (if known): K062383

Device Name: UniSyn Modular Hip System

Indications For Use:

Indications for use of the UNISYN™ HIP SYSTEM
A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
B) Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
C) Proximal femoral fractures.
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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 K062383