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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the ATH Femoral Stem.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 19, 2003
Contact Person:	Jeanine H. Redden Regulatory Affairs Associate
Proprietary Name:	ATH Femoral Stem
Common Name:	HIP PROSTHESIS
Classification Name and Reference:	21 CFR 888.3358 Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented– Class II 21 CFR 888.3350 Prosthesis, hip, semi-constrained, metal/polymer, cemented– Class II
Device Product Code and Panel Code:	Orthopedics/87/LPH/JDI

DEVICE INFORMATION

A. INTENDED USE

The ATH Femoral Stem is 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:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of fractures that are unmanageable using other techniques.

B. DEVICE DESCRIPTION

The design features for Wright Medical Technology's ATH Femoral Stem are as follows:

- Sizes range from 4mm to 13mm
- Wright Medical Technology's standard 12/14 SLT taper
- Grit blast surface finish

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011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

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- Proximal body with double wedge shape
- Proximal body has rounded off rectangular cross-section
- Tapered distal stem with rounded off rectangular cross-section
- Dimple on lateral shoulder

C. SUBSTANTIAL EQUIVALENCE INFORMATION

Wright Medical Technology's ATH Femoral Stem is substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of the ATH Femoral Stem is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2004

Ms. Jeanine H. Redden
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K034028
Trade/Device Name: ATH Femoral Stem Implant
Regulation Numbers: 21 CFR 888.3350 and 21 CFR 888.3358
Regulation Names: Spinal interlaminal fixation orthosis, Hip joint metal/polymer/metal semi-constrained pouous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: JDI and LPH
Dated: February 20, 2004
Received: February 23, 2004

Dear Ms. Redden:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for 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

Indications for Use

510(k) Number: K034028

Device Name: ATH Femoral Stem

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

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