AUG 2 5 2009

K091423

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

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 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Hip System Modular Necks.

Submitted By:	Wright Medical Technology, Inc.
Date:	April 16, 2009
Contact Person:	Ryan Ross *Regulatory Affairs Specialist II*
Proprietary Name:	PROFEMUR® Hip System Modular Necks
Common Name:	Modular Neck
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component, prosthesis Class III 21 CFR 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis Class III 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Class II 21 CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, semi-constrained, metal/polymer, uncemented Class II
Subject Device Product Code and Panel Code:	Orthopedics/87/ KWA, JDL, LZO, LWJ, LPH, MBL

DEVICE INFORMATION

A. Intended Use

The PROFEMUR® Hip System Modular Necks are 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; and,
4. revision procedures where other treatments or devices have failed

Modular necks can be used during either cemented or uncemented femoral and acetabular arthroplasty.

B. Device Description

The design features of the PROFEMUR® Hip System Modular Necks are summarized below:

- Manufactured from Cobalt Chrome Alloy
- 12/14 SLT tapered cone for modular femoral head connection
- Offered in two length options
- Each length option is offered in six versions

C. Substantial Equivalence Information

The indications for use of the PROFEMUR® Hip System Modular Necks are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® Hip System Modular Necks are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Mr. Ryan Ross
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

AUG 2 5 2009

Re: K091423
Trade/Device Name: Profemur Hip System Modular Necks
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, JDL, LWJ, LPH, MBL, LZO
Dated: August 17, 2009
Received: August 18, 2009

Dear Mr. Ross:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091423

Device Name: PROFEMUR® Hip System Modular Necks

Indications For Use:

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091423