K100306

WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company

APR 28 2010

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

(a)(1) Submitted By
The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Submitter's Name:	Wright Medical Technology, Inc. 5677 Airline Rd. Arlington, TN 38002 800-238-7188 (phone), 901-867-4190 (fax)
Date:	April 28, 2010
Contact Person:	Gregory Neal Regulatory Affairs Specialist II

(a)(2) Device Name
Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name if known:

Proprietary Name:	PROFEMUR® Hip System Modular Necks
Common Name:	Modular Neck
Classification Name and Reference:	21 CFR 888.3353 Hip joint metal/ ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. Class II
Subject Device Product Code and Panel Code:	Orthopedics/87/ LZO

(a)(3) Predicate Device
Identification of the legally marketed device to which the submitter claims equivalence:

Predicate Proprietary Name: **Predicate Classification and Number:**	PROFEMUR® Hip System Modular Necks 888.3330 KWA Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis Class III 510(k) K091423
	PROFEMUR® LX 5/8 Coated Hip Stem 888.3353 LZO Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II 510(k) K081090
	CERAMIC FEMORAL HEAD 888.3353 LZO Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II 510(k) K893685

(a)(4) Device Description
Description of the device that is the subject of the premarket notification submission:

The subject modular femoral necks, manufactured from cobalt chrome alloy, were cleared for use in K091423 with metal femoral heads, but lacked testing for direct assembly to ceramic femoral heads. This 510(k) notification consists of the mechanical testing that allows for the clearance for use of the subject necks with the 28mm, 32mm, and 36mm alumina ceramic femoral heads previously cleared in K893685, and removal of this previous contraindication (K091423), except for with the 28mm Long ceramic head.

Mean and minimum pre-fatigue burst strength testing results exceeded minimum values specified by FDA in the *Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems* – 1/10/95. Mean post-fatigue burst strength and mean axial static distraction force per ASTM F2009 was greater than that of the identical currently marketed ceramic femoral heads assembled to a titanium neck cone. Harder identical taper junctions demonstrated less fretting than softer identical junctions. Lower hardness identical junctions demonstrated resistance to fatigue failure per ISO 7206-6. Total Fretting wear for proximal and distal junctions was less than that of published metal-on-metal articulating wear results.

(a)(5) Intended Use of the Device
Statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended:

Intended Use

The PROFEMUR® Hip System Modular Necks are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

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.

(a)(6) Technological Characteristics of the Device
Summary of the technological characteristics of the new device in comparison to those of the predicate device:

The indications for use for the subject PROFEMUR® Hip System Cobalt Chrome Modular Necks are identical to the indications previously cleared for the Predicate Device (K091423). The identical intended use for ceramic heads with a metal femoral component was cleared for the modular PROFEMUR® LX 5/8 Hip Stem (K081090). The design and materials of the PROFEMUR® Hip System Cobalt Chrome Modular Necks are unchanged from the design presented in K091423. The design and materials of the Ceramic Femoral Heads are unchanged from the design presented in K893685.

(b)(1) Nonclinical Testing
Brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:

PROFEMUR® Hip System Modular Necks meet requirements per pre and post-fatigue burst strength testing specified by FDA in the *Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*; per static, fatigue, and post-fatigue compressive burst testing of 28mm alumina ceramic heads conducted in accordance with ASTM 2345-03 - Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads; per axial static distraction of ceramic femoral heads conducted in accordance with ASTM F2009-00 - Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses; per ISO 7206-6 Partial and total hip joint prostheses—Part 6: Determination of endurance properties of head and neck region of stemmed femoral components; per ISO: 11135 Sterilization of health care products- Requirements for development, validation and routine control of sterilization process for medical devices-Ethylene oxide; per ISO: 11137 Sterilization of health care products- Requirements for development, validation and routine control of sterilization process for medical devices-Radiation sterilization; per ASTM F1537 Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants, and per ISO 6474 Ceramic Materials Based on High Purity Alumina.

(b)(2) Clinical Testing
Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:

Clinical data was not provided for the class II modular neck devices.

(b)(3) Conclusions
Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in (a)(3):

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 unchanged. 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

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Mr. Gregory Neal
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Texas 38002

APR 28 2010

Re: K100866
Trade/Device Name: PROFEMUR® Hip System Modular Necks
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: March 23, 2010
Received: March 29, 2010

Dear Mr. Neal:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehler

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

Enclosure

WRIGHT.

Indications

510(k) Number: K100866

Device Name: PROFEMUR® Hip System Modular Necks

Indications For Use

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.

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 MXM

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

510(k) Number K100866