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DEC 2 2 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, this information serves as a Summary of Safety and Effectiveness for the use of the Anterior Approach Hip Surgery Instruments.

(a)(1) Submitted By

Submitter's Name:	Wright Medical Technology, Inc. 5677 Airline Rd. Arlington, TN 38002 800-238-7188 (phone), 901-867-4190 (fax)
Date:	December 20, 2010
Contact Person:	Gregory Neal Regulatory Affairs Specialist II

(a)(2) Device Name

Proprietary Name:	Anterior Approach Hip Surgery Instruments
Common Name:	Broach, Inserter/Impactor, Chisel, Rasp
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III
Subject Device Product Code and Panel Code:	Orthopedics/87/KWA, JDI, JDL, LWJ, LZO

(a)(3) Predicate Device

Predicate Proprietary Name:	PROFEMUR® LX 5/8 Hip Stem (K081090) PROFEMUR® TL Hip Stem (K060358)
Predicate Classification and Number:	Orthopedics/87/ KWA, 888.3330

(a)(4) Device Description

The design features of the Anterior Approach Hip Surgery Instruments are summarized below:

- Manufactured from Stainless Steel
- Modular PROFEMUR® Starter Broach – provides means to begin preparation of proximal femur; overall size envelope is smaller than any existing PROFEMUR® stem, allowing usage with all designs; curvature of lateral surface allows insertion without interfering with greater trochanter; engagement with broach handle allows usage in familiar orientation
- Modular PROFEMUR® Box Chisel – provides means to remove bone in calcar region, creating opening for other instruments; curvature of lateral surface allows insertion without interfering with greater trochanter; engagement with broach handle allows usage in familiar orientation

- Modular PROFEMUR® Dimple Stem Inserter – provides means by which implant may be impacted via engagement of dimple on lateral shoulder; engagement with broach handle allows usage in familiar orientation
- Modular PROFEMUR® Pocket Stem Inserter – provides means by which implant may be impacted via engagement of modular neck pocket; engagement with broach handle allows usage in familiar orientation
- Lateralizing Rasp – provides rigid, aggressively-toothed surface at end of handle that can be used to contour the proximal region of the femoral canal.
- Dual-Offset Broach Handles – Right and Left broach handles provide improved access to the proximal femur

(a)(5) Intended Use

The Wright Total Hip Implant Stems for use with these instruments 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

(a)(6) Technological Characteristics of the Device

The indications for implants used with the Anterior Approach Hip Surgery Instruments are identical to instruments used with implants cleared by PROFEMUR® LX 5/8 Hip Stem and PROFEMUR® TL Hip Stem. Materials for the Anterior Approach Hip Surgery Instruments are identical to instruments used with implants cleared by PROFEMUR® TL Hip Stem. The design features of the Anterior Approach Hip Surgery Instruments are substantially equivalent to the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices.

(b)(1) Nonclinical Testing

Prototypes were used and further evaluated by the design surgeons in a surgical setting.

(b)(2) Clinical Testing

Clinical data was not provided for the Class I instruments.

(b)(3) Conclusions

The safety and effectiveness of the Anterior Approach Hip Surgery Instruments 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 M. Neal
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, TN 38002

DEC 2 2 2010

Re: K102565
Trade/Device Name: Anterior Approach Hip Surgery Instruments
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDI, JDL, LWJ, LZO
Dated: November 24, 2010
Received: November 26, 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

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,

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

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Anterior Approach Hip Surgery Instruments

Indications For Use:

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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____ 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 M. Melkerson

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

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