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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 10 2011

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® Gladiator HA Hip Stems.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	September 30, 2011
Contact Person:	Matt Paul *Project Regulatory Affairs Specialist*
Proprietary Name:	PROFEMUR® X^{m} Wingless Distal Centralizer PERFECTA® Distal Centralizer
Common Name:	Centralizer
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis Class III
Subject Product Code and Panel Code:	Orthopedics/87/KWA, JDL, LZO, JDI
Predicate Devices Name and Number:	PROFEMUR® X^{M} (PROFEMUR XTR) NEXUS™ Femoral Hip Stem 510(k): K052915, K911052
Predicate Classification and Number:	Orthopedics/87/ KWA, 888.3330

DEVICE INFORMATION

A. Device Description

The PROFEMUR® X^{m} Wingless Distal Centralizer and PERFECTA® Distal Centralizer are molded PMMA centralizers placed within the femoral canal before the hip stem implant, providing a guide for the implant and allowing the surgeon to easily center the hip stem implant within a uniformly thick cement mantle. The centralizer bears no body weight, since the cured bone cement transfers all loading forces from the stem to the bone. The materials used for the Distal Centralizers are identical to the materials used for the predicate devices (molded PMMA), but unlike the predicate the replacement will not contain any additives. The following tests on the predicate apply to the subject material: Kligman sensitization, intracutaneous injection, systemic injection, reverse mutagen assay, chromosomal aberration assay, rodent micronucleus assay, and a 4-week bone implantation assay.

The subject material for the PROFEMUR® X^{m} Wingless Distal Centralizer and PERFECTA® Distal Centralizer was evaluated via mechanical testing (compressive strength), residual monomer analysis (HPLC), molecular weight analysis (GPC), and cytotoxicity. A review of these results indicates that

the PROFEMUR® X^m Wingless Distal Centralizer and PERFECTA® Distal Centralizer are equivalent to predicate devices and are capable of withstanding expected *in vivo* conditions without failure.

B. Intended Use

Wright Distal Centralizers are intended for use in cemented 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

Wright Distal Centralizers are indicated for cemented hip arthroplasty.

C. Technological Characteristics of the Device

The PROFEMUR® X^m Wingless Distal Centralizer and PERFECTA® Distal Centralizer have the same technological characteristics as the predicate devices. The PMMA Distal Centralizers are placed on the distal end of the hip stem implant during its final insertion into the bone, providing a guide for the implant and allowing the surgeon to easily center the hip stem implant within the femoral canal, and thereby allow a uniformly thick cement mantle. The centralizer bears no body weight, since the cured bone cement transfers all loading forces from the stem to the bone. The material used for the Distal Centralizers identically conforms to ASTM F451 as does the material used for the predicate devices (molded PMMA), but unlike the predicate the replacement will not contain any additives.

D. Nonclinical Testing

The PROFEMUR® X^m Wingless Distal Centralizer and PERFECTA® Distal Centralizer have been tested by mechanical testing (compressive strength), residual monomer analysis (HPLC), molecular weight analysis (GPC), differential scanning calorimetry, FTIR, NMR, GC-MS, and cytotoxicity

E. Clinical Testing

Clinical data was not provided for the centralizers.

F. Conclusions

The indications for use of the PROFEMUR® X^m Wingless Distal Centralizer and PERFECTA® Distal Centralizer are identical to the previously cleared predicate devices. The design features of the devices are unchanged. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® X^m Wingless Distal Centralizer and PERFECTA® Distal Centralizer 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

NOV 10 2011

Wright Medical Technology, Inc.
% Matt Paul
5677 Airline Rd
Arlington, TN 38002

Re: K113019
Trade/Device Name: Profemur X^{m} Wingless Distal Centralizers
Perfecta Distal Centralizers
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, JDL, LZO, JDI
Dated: September 30, 2011
Received: October 11, 2011

Dear Mr. Paul:

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,

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

Enclosure

WRIGHT.

K113019

Indications for Use

Device Name: PROFEMUR® X[m] Wingless Distal Centralizer
PERFECTA® Distal Centralizer

Indications For Use:

The PMMA Distal Centralizers are intended 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

The PMMA Distal Centralizers are single use components, intended for use as part of a cemented total hip 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)

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

510(k) Number K113019