

K121221

AUG 9 2012

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® Z Revision Hip Stem .

Submitted By: Wright Medical Technology, Inc.
5677 Airline Rd, Arlington TN, 38002
(800) 238-7188

Date: February 7, 2012

Contact Person: Yuan Li, Ph.D
Regulatory Affairs Specialist

Proprietary Name: PROFEMUR® Z Revision Hip Stem

Common Name: Hip Stem

Classification Name and Reference: 888.3353 LZO Hip joint metal/ceramic/ polymer,
cemented or non-porous, uncemented
prosthesis Class II

888.3350 JDI Hip joint metal/polymer semi-
constrained cemented prosthesis Class II

Subject Product Code and Panel Code: Orthopedics/87/LZO, JDI

Predicate Devices: STEM Hip Replacement System
510(k)s: K021346

PRESERVE HIP STEM
510(K): K112080

DEVICE INFORMATION

A. Intended Use

Wright Medical total hip systems are indicated 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

The PROFEMUR® Z Revision Hip Stem is intended for cementless hip arthroplasty.

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B. Device Description

Design features of the subject stems are summarized below:

- Cementless modular stems
- Available in 9 sizes
- Manufactured from Titanium alloy with a heavy grit blasted surface

The subject device is available in 9 sizes (from size 3 to 11). Although the proximal geometries are identical to the predicate from size 3-9, the distal stem length has increased, with two larger sizes (10 and 11) introduced.

C. Nonclinical Testing

The PROFEMUR® Z Revision Hip Stems have been tested in distal and proximal fatigue evaluation per the loading regimen prescribed by ISO 7206-4, -6 and -8.

D. Clinical Testing

Clinical data was not provided for the class II hip stem.

E. Conclusions

The indications for use of the PROFEMUR® Z Revision Hip Stems 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 devices has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® Z Revision Hip Stem is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



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

Wright Medical Technology, Inc.
% Mr. Yuan Li
5677 Airline Rd.
Arlington, TN 38002 US

AUG 9 2012

Re: K121221

Trade/Device Name: Profemur Z Revision Hip Stem

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip Joint Metal/Ceramic/Polymer Cemented or Non-Porous Uncemented
Prosthesis

Regulatory Class: Class II

Product Code: LZO, JDI

Dated: July 9, 2012

Received: July 10, 2012

Dear Mr. Li:

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

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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 & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121221

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® Z Revision Hip Stem

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
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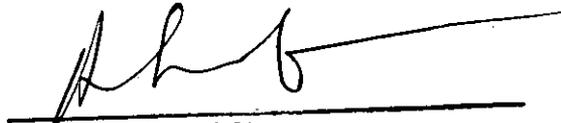
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)



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

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