

K041114



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MAY 28 2004

**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® Tapered Hip Stem.

Submitted By: Wright Medical Technology, Inc.
 Date: April 26, 2004
 Contact Person: Katie Logerot
 Regulatory Affairs Specialist II
 Proprietary Name: PROFEMUR® Tapered Hip Stem
 Common Name: Hip Stem
 Classification Name and Reference: Prosthesis, hip, semi-constrained, metal/polymer, uncemented – Class II
 21CFR 888.3350 Hip joint metal/polymer, semi-constrained, cemented prosthesis - Class II
 Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented – Class II
 21 CFR 888.3320 Hip joint metal/ metal semi-constrained, with a cemented acetabular component prosthesis – Class III
 21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III
 Device Product Code and Panel Code: Orthopedics/87/ LWJ, JDI, LZO, JDL, KWA

DEVICE INFORMATION

A. INTENDED USE

The PROFEMUR® Tapered Hip Stem is 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:

headquarters

Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 901.867.9971 phone

www.wmt.com

international subsidiaries

011.32.2.378.3905 Belgium

905.826.1600 Canada

011.33.1.45.13.24.40 France

011.49.4161.745130 Germany

011.39.0250.678.227 Italy

011.81.3.3538.0474 Japan

011.44.1483.721.404 UK

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

B. DEVICE DESCRIPTION

The design features of the PROFEMUR® Tapered Hip Stem are summarized below:

- Modular neck taper
- Tapered cylindrical distal stem
- Plasma Sprayed proximal body
- Grit blasted distal stem
- Polished bullet tip
- Spines

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use and materials of the PROFEMUR® Tapered Hip Stem are identical to the PROFEMUR® Z Hip Stem. The design features of the PROFEMUR® Tapered Hip Stem are substantially equivalent to the PROFEMUR® Z Hip Stem, the PERFECTA® RS Hip Stem, and the PERFECTA® Plasma Sprayed Hip Stem. The safety and effectiveness of the PROFEMUR® Tapered Hip Stem are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2004

Ms. Katie Logerot
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K041114

Trade/Device Name: PROFEMUR[®] Tapered Hip Stem

Regulation Numbers: 21 CFR 888.3320, 21 CFR 888.3330, 21 CFR 888.3350, and
21CFR 888.3353

Regulation Names: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis and Prosthesis, hip, semi-constrained, metal/polymer, uncemented

Regulatory Class: III

Product Codes: JDL, KWA, JDI, LZO and LWJ

Dated: April 26, 2004

Received: April 28, 2004

Dear Ms. Logerot:

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 such 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.

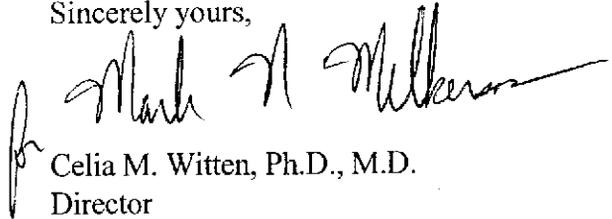
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K04 1114

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® Tapered Hip Stem

Indications For Use:

The PROFEMUR® Tapered Hip Stem is 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,
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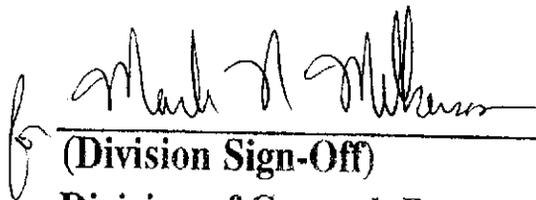
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)

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(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

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