

K041586 (pg 1 of 2)

**510(K) SUMMARY  
OF SAFETY AND EFFECTIVENESS**

**JUL 09 2004**

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® S Hip Stem.

Submitted By: Wright Medical Technology, Inc.  
Date: July 6, 2004  
Contact Person: Jeanine H. Redden  
Regulatory Affairs Specialist II  
Proprietary Name: PROFEMUR® S 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® S 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:**

K041586 (pg 2 of 2)

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® S Hip Stem are summarized below:

- Offered in two medial flare options
- Modular neck taper
- Triplanar proximal geometry w/ plasma spray
- Splined, slotted, and cylindrical distal stem w/ grit blast
- Dimple with cross slot on lateral shoulder
- Polished distal tip and collar

## **C. SUBSTANTIAL EQUIVALENCE INFORMATION**

The indications for use and materials of the PROFEMUR® S Hip Stem are identical to the PERFECTA® RS and PROFEMUR® R Hip Stems. The design features of the PROFEMUR® S Hip Stem are substantially equivalent to the PERFECTA® RS, PROFEMUR® R, and PROFEMUR® Tapered Hip Stems. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® S 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

JUL 09 2004

Ms. Jeanine H. Redden  
Regulatory Affairs Specialist II  
Wright Medical Technology, Inc.  
5677 Airline Road  
Arlington, Tennessee 38002

Re: K041586

Trade/Device Name: PROFEMUR® S Hip Stem

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

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: June 9, 2004

Received: June 14, 2004

Dear Ms. Redden:

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" (21CFR 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,



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

## Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® S Hip Stem

### Indications For Use:

**The PROFEMUR® S 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,
4. revision procedures where other treatments or devices have failed

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

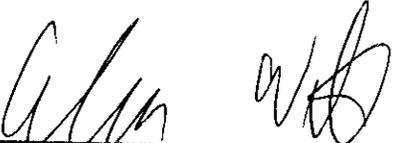
AND/OR

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 General, Restorative,  
and Neurological Devices

Page 1 of  1

510(k) Number  K041586