

APR - 8 2008

**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® LX Revision 5/8 Coated Hip Stem.

Submitted By: Wright Medical Technology, Inc.
Date: January 24, 2008
Contact Person: Ryan Ross
Regulatory Affairs Specialist
Proprietary Name: PROFEMUR® LX Revision 5/8 Coated Hip Stem
Common Name: Hip Stem
Classification Name and Reference: 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/ KWA, LZO, MBL

DEVICE INFORMATION

A. Intended Use

The PROFEMUR® LX Revision 5/8 Coated 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

The PROFEMUR® LX Revision 5/8 Coated Hip Stem is intended to be used in cementless total hip arthroplasty.

B. Device Description

The design features of the PROFEMUR® LX Revision 5/8 Coated Hip Stem are summarized below:

- Manufactured from titanium alloy (Ti₆Al₄V)
- Proximal 5/8 of stem plasma sprayed
- Offered in Sizes 13-21
- Polished distal tip and collar
- Threaded hole with slot impaction mechanism

C. Substantial Equivalence Information

The indications for use of the PROFEMUR® LX Revision 5/8 Coated Hip Stem 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 device has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® LX Revision 5/8 Coated Hip Stem is 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

APR - 8 2008

Wright Medical Technology, Inc.
% Mr. Ryan Ross
5677 Airline Road
Arlington, TN 38002

Re: K080663
Trade/Device Name: Profemur LX Revision 5/8 Coated Hip Stem
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, LZO, MBL
Dated: January 24, 2008
Received: March 10, 2008

Dear Mr. Ross:

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.

Page 2 – Mr. Ryan Ross

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
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® LX Revision 5/8 Coated Hip Stem

Indications For Use:

The PROFEMUR® LX Revision 5/8 Coated 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:

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The PROFEMUR® LX Revision 5/8 Coated Hip Stem is intended to be used in cementless total hip arthroplasty.

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)

Neil A. P. Ogden for xxxx
(Division Sign-Off)

**Division of General, Restorative
and Neurological Devices**

510(k) Number K080663