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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 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® LX Hip Stem.

Submitted By:	Wright Medical Technology, Inc.
Date:	January 11, 2006
Contact Person:	Theresa Leister Regulatory Affairs Specialist II
Proprietary Name:	PROFEMUR® LX Hip Stem
Common Name:	Hip Stem
Classification Name and Reference:	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 21 CFR 888.3353 Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented– Class II
Device Product Code and Panel Code:	Orthopedics/87/ LZO, JDL, KWA

DEVICE INFORMATION

A. INTENDED USE

The PROFEMUR® LX 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

B. DEVICE DESCRIPTION

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

- Manufactured from titanium alloy (Ti6Al4V)
- Offered in one medial flare option
- Tri-planar proximal geometry with plasma sprayed surface
- Cylindrical, splined, and slotted distal stem with glassbead surface
- Threaded hole with slot impaction mechanism
- Polished distal tip and collar

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use of the PROFEMUR® LX Hip Stem are identical to the predicate devices. The design features of the PROFEMUR® LX Hip Stem 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 Hip Stem 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
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Theresa Leister
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K053588
Trade/Device Name: PROFEMUR® LX Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: III
Product Code: KWA, LZO, JDL
Dated: December 22, 2005
Received: December 23, 2005

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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), they 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.

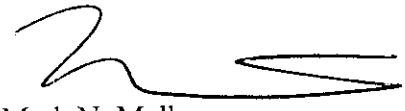
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:ELF:rrr: 1/12/06

K053588

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® LX Hip Stem

Indications For Use:

The PROFEMUR® LX 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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2. inflammatory degenerative joint disease such as rheumatoid arthritis;
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4. revision procedures where other treatments or devices have failed

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 General, Restorative, and Neurological Devices

510(k) Number K053588