K012091

1 OF 2

OCT - 3 2001

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

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 PRO-FEMUR Hip System.

Submitted By:	Wright Medical Technology, Inc.
Date:	July 3, 2001
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs
Proprietary Name:	PRO-FEMUR
Common Name:	TOTAL HIP SYSTEM
Classification Name and Reference:	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENT – Class II PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/POLYMER, CEMENTED OR NON-POROUS, UNCEMENTED– Class II
Device Product Code and Panel Code:	Orthopedics/87/ LWJ and LZO

DEVICE INFORMATION

A. INTENDED USE

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;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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The PRO-FEMUR Hip System are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

B. DEVICE DESCRIPTION

The PRO-FEMUR Hip with plasma spray coating is a modular prosthesis comprising of four principal parts:

- Distal Stem
- Proximal Body
- Extension Adapter
- Modular Neck

The PRO-FEMUR distal stem with plasma spray coating will be available in three different lengths, namely SHORT, MEDIUM, and LONG, in increments of 1mm from 10mm to 22mm in diameter. The SHORT distal stem (135mm) is straight, and the MEDIUM (175mm) and LONG (215mm) are both anatomically curved. All distal stems are cylindrical with plasma spray coating and a bullet shaped distal tip.

The PRO-FEMUR Proximal Body with plasma spray coating will be available in seven different sizes: Extra Small, Small, 4x Standard, and Large. The four standard components have the same length but became progressively wider.

The distal stem is secured to the proximal body by a morse taper and secondly by a fixation screw.

To further lengthen the implant by either 26 or 52 mm, extension adapters are available. They are positioned between the selected proximal body and distal stem and secured by morse taper and a longer fixation screw.

The proximal body has a specific oblong housing for the insertion of the twelve modular necks.

The design features of PRO-FEMUR Hip System with plasma spray coating are substantially equivalent to the design features of competitive devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of PRO-FEMUR Hip System are substantially equivalent to the competitive devices previously cleared for market. The safety and effectiveness of the PRO-FEMUR Hip System are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

WRIGHT
MEDICAL TECHNOLOGY, INC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K012091
Trade/Device Name: PRO-FEMUR Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ, MAY
Dated: July 3, 2001
Received: July 5, 2001

Dear Mr. Esmail:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Milhern

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

K012091

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

PRO-FEMUR
HIP SYSTEM

INDICATIONS STATEMENT

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;
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4) revision procedures where other treatments or devices have failed; and,
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(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 Devices
510(k) Number _____

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K012091

WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company