K003016

DEC 13 2000

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 R Revision Hip System.

Submitted By:	Wright Medical Technology, Inc.
Date:	September 26, 2000
Contact Person:	Ehab M. Esmail Senior Regulatory Affairs Associate
Proprietary Name:	PRO-FEMUR R
Common Name:	REVISION HIP SYSTEM
Classification Name and Reference:	21 CFR 888.3358 Prosthesis, Hip, Semi-Constrained, metal/polymer, Uncemented – Class II
Device Product Code and Panel Code:	Orthopedics/87/LPH

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 R Revision 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 R Revision Hip System is a modular prosthesis comprising of four principal parts:

- Distal stem with cutting flanges for the diaphyseal fixation
- Extension Adapter
- Proximal body for support in the metaphyseal region
- Modular neck

The PRO-FEMUR R distal stem 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 slightly conical in profile and feature cutting flanges that provide excellent primary fixation. The cutting flanges are absent on the anterior and posterior curvature of the stem in order to reduce the possibility of femoral fracture during impaction.

The PRO-FEMUR R Proximal Body 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 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 which are available in six versions and two lengths: Neutral, antiversion/ retroversion 8° or 15°, varus/ valgus 8°, or combination of anteverted/ retroverted - varus/ valgus (in both short and long lengths)

The design features of PRO-FEMUR R Revision Hip System are substantially equivalent to competitive devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2000

Mr. Ehab M. Esmail
Senior Regulatory Affairs Associate
Wright Medical Technology Incorporated
5677 Airline Road
Arlington, Tennessee 38002

Re: K003016
Trade Name: Pro-Femur R Revision Hip System
Regulatory Class: II
Product Code: LWJ
Dated: September 26, 2000
Received: September 27, 2000

Dear Mr. Esmail:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhorn

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

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5677 AIRLINE ROAD
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PROFEMUR R
REVISION HIP SYSTEM

INDICATIONS STATEMENT

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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 ____ OR Over-The Counter Use ____
(Per21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003016