K031402

NOV 2 2 2004

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 PERFECTA® Femoral Stem.

Submitted By:	Wright Medical Technology, Inc.
Date:	May 2, 2003
Contact Person:	Ehab M. Esmail Senior Manager, Regulatory Affairs
Proprietary Name:	PERFECTA® Femoral Stem
Common Name:	TOTAL HIP SYSTEM
Classification Name and Reference:	21CFR 888.3358 Hip joint metal/polymer/metal, semi-constrained porous coated uncemented prosthesis 21CFR 888.3350 Hip joint metal/polymer, semi-constrained, cemented prosthesis –Class II
Device Product Code and Panel Code:	Orthopedics/87/ LPH, and JDI

DEVICE INFORMATION

A. INTENDED USE

The PERFECTA® Femoral Stem with calcium sulfate coating 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;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of fractures that are unmanageable using other techniques.

The PERFECTA® Femoral Stem with calcium sulfate coating is for single use only, and is intended for use in conjunction with existing Wright Medical Technology ceramic or metal femoral heads, acetabular liners and shells, as a part of an uncemented total hip arthroplasty.

B. DEVICE DESCRIPTION

The design features and functions of the PERFECTA® Femoral Stem with calcium sulfate coating will be identical to the design features and functions of the currently available PERFECTA® Femoral Stem (510(k): K991123 and K004032), with the exception of the calcium sulfate coating.

All femoral stems will be available in a range of sizes (9-22.5 mm) and will feature the same Wright Medical Technology (SLT) 12/14 taper.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the PERFECTA® Femoral Stem with calcium sulfate coating are substantially equivalent to the PERFECTA® Femoral Stems previously cleared for market (510(k): K991123 and K004032).

The safety and effectiveness of the PERFECTA® Femoral Stem with calcium sulfate coating are adequately supported by the substantial equivalence information, materials data, and functional animal model that are provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

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

Re: K031402
Trade/Device Name: Calcium Sulfate Coated Perfecta® Femoral Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: August 20, 2004
Received: August 24, 2004

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), please contact the Office of Compliance at (240) 276-0120. 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, PhD, MD
Director
Division of General, Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PERFECTA® Femoral Stem

INDICATIONS STATEMENT

510(k) Number (if known):

Device Name: PERFECTA® Femoral Stem

Indications For Use:

The PERFECTA® Femoral Stem with calcium sulfate coating 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;
4. revision procedures where other treatments or devices have failed; and,
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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

510(k) Number K031402

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