



APR 18 2005

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 ADVANCE® HA Coated Spiked Tibial Base and the ADVANCE® HA Coated Modular Keel.

Submitted By:	Wright Medical Technology, Inc.
Date:	November 5, 2004
Contact Person:	Ehab M. Esmail Sr. Manager, Regulatory Affairs
Proprietary Name:	ADVANCE® HA Coated Spiked Tibial Base and the ADVANCE® HA Coated Modular Keel
Common Name:	HA COATED COMPONENTS
Classification Name and Reference:	21 CFR 888.3565 Prosthesis, Knee, Patello/femorotibial, Semi-Constrained, Uncemented, Porous Coated, Polymer/Metal/Polymer – Class II
Device Product Code and Panel Code:	Orthopedics/87/ MBH

DEVICE INFORMATION

A. INTENDED USE

The ADVANCE® HA Coated Components are indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including 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.

headquarters

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011.81.3.3538.0474 Japan

011.33.1.45.13.24.40 France
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011.49.4161.745130 Germany

The ADVANCE® HA Coated Components are for use without bone cement and are single use devices.

B. DEVICE DESCRIPTION

The ADVANCE® HA Coated Components are an HA Coated Spiked Tibial Base and an HA Coated Modular Keel. The design features of the components are described below.

ADVANCE® HA Coated Spiked Tibial Base

- 4 spikes on the distal surface
- Manufactured from titanium alloy
- Titanium sintered bead porous coated
- HA coated

ADVANCE® HA Coated Modular Keel

- 2 small anterior fins
- 2 posterior fins
- Manufactured from titanium alloy
- HA coated

The design features of ADVANCE® HA Coated Components are substantially equivalent to the design features of other devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, and design features of ADVANCE® HA Coated Components are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of ADVANCE® HA Coated Components are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K043083

Trade/Device Name: ADVANCE® HA Coated Spiked Tibial Base and the ADVANCE®
HA Coated Modular Keel

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented
prosthesis

Regulatory Class: II

Product Code: MBH

Dated: March 25, 2005

Received: March 28, 2005

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.

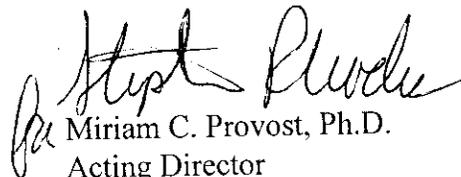
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Mr. Ehab M. Esmail

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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is written in a cursive style with a small "M" at the beginning.

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043083

Indications for Use

510(k) Number (if known):

Device Name: ADVANCE® HA Coated Spiked Tibial Base and ADVANCE® HA Coated Modular Keel

Indications For Use:

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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)

Steph Pluck
(Division Sign-Off)

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

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