K063128

MAR 2 1 2007

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 ADVANCE® Spiked Porous Tibial Base.

Submitted By:	Wright Medical Technology, Inc.
Date:	October 11, 2006
Contact Person:	Theresa Leister Regulatory Affairs Specialist II
Proprietary Name:	**ADVANCE® Spiked Porous Tibial Base**
Common Name:	Tibial Base
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® Spiked Porous Tibial Base is 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.

The ADVANCE® Spiked Porous Tibial Base is for use without bone cement and is a single use device.

B. DEVICE DESCRIPTION

The design features of the ADVANCE® Spiked Porous Tibial Base are described below.

- 4 spikes on the distal surface
- Available with or without screw holes
- Manufactured from titanium alloy
- Titanium porous coating

The design features of ADVANCE® Spiked Porous Tibial Base are substantially equivalent to the design features of other devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the ADVANCE® Spiked Porous Tibial Base are substantially equivalent to previously cleared predicate devices. The safety and effectiveness of the ADVANCE® Spiked Porous Tibial Base is 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

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

MAR 2 1 2007

Re: K063128
Trade/Device Name: ADVANCE Spiked Porous Tibial Base
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: March 8, 2007
Received: March 9, 2007

Dear Ms. Leister:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K063128

Device Name: ADVANCE® Spiked Porous Tibial Base

Indications For Use:

The ADVANCE® Spiked Porous Tibial Base is 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:

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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)

Barbara Burkhead

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

510(k) Number K063128