FEB 20 2009

K081479

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® A-CLASS® Tibial Base

Submitted By:	Wright Medical Technology, Inc.
Date:	May 9, 2008
Contact Person:	Fred W. Bowman, P.E. Senior Regulatory Affairs Specialist
Proprietary Name:	**ADVANCE® A-CLASS® Insert**
Common Name:	Tibial Insert
Classification Name and Reference:	21 CFR 888.3560 Knee, Patellofemorotibial, Semi-constrained, cemented, Polymer/ metal/polymer 21 CFR 888.3565 Knee, patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Device Product Code and Panel Code:	Orthopedics/87/ JWH Orthopedics/87/ MBH

DEVICE INFORMATION

A. INTENDED USE

The ADVANCE A-CLASS Tibial Insert is indicated for use with the Advance Total Knee system 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 A-CLASS Insert is for single use. The Advance Total Knee System porous components are for use without bone cement. The Advance Total Knee System non-porous components are for use with bone cement.

B. DEVICE DESCRIPTION

The design features of the ADVANCE® A-CLASS® Tibial Insert are summarized below:

- Articulating Surface: Medial Pivot rotation
- Lock Detail: Perimeter capture with central dove tail
- Size Range: Sizes 1-6, thicknesses of 10mm-25mm
- Material: Cross-Linked GRU1020 UHMWPE

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the ADVANCE® A-CLASS® Tibial Insert are substantially equivalent to the design features, excluding material, of the ADVANCE® Medial Pivot Tibial Insert. The material of the ADVANCE® A-CLASS® Tibial Insert is substantially equivalent to the material of the LINEAGE® A-CLASS® Acetabular Liner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Mr. Fred W. Bowman, P.E.
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

FEB 20 2009

Re: K081479
Trade/Device Name: ADVANCE® A-CLASS Tibial Insert
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH, JWH
Dated: January 30, 2009
Received: February 2, 2009

Dear Mr. Bowman:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

For Mark N. Melkerson 2/20/09

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):

Device Name: ADVANCE® A-CLASS Tibial Insert

Indications For Use:

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Prescription Use __xxx__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

1 of 1

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

510(k) Number k081479