K972626
Sept. 29, 1997

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

Contact Person: Dan Regan
Date Prepared: July 11, 1997

510(k) SUMMARY

Trade Name:	ADVANCE® knee system components
Common Name:	Total Knee Replacement Implant
Product Classification:	II
Predicate Device:	Axiom Total Knee System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Intended Use
The ADVANCE® knee system components consists of femoral and modular tibial inserts intended to be used only with bone cement.

The ADVANCE® knee system components are indicated in total knee replacements for 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.

Materials

The ADVANCE® femoral component is manufactured from cobalt chrome alloy. The tibial components are manufactured from ultra high molecular weight polyethylene.

Testing Summary
- Submitted patella-femoral contact area testing demonstrates that the ADVANCE® knee system component is comparable to the predicate device.
- Submitted femoral-tibial contact area testing demonstrates that the ADVANCE® knee system component is comparable to the predicate device.
- Submitted patella-femoral lateral stability testing demonstrates that the ADVANCE® knee system component resists lateral subluxation similar to the predicate device.
- Submitted femoral-tibial constraint testing (anterior shear, posterior shear, medial shear, lateral shear, and rotation) demonstrates that the ADVANCE® knee system component is expected to remain stable and resist displacement when subjected to appropriate physiological loads.
- Submitted ultra high molecular weight polyethylene (UHMWPE) properties demonstrate that the ADVANCE® polyethylene components should perform adequately.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1997

Mr. Dan Regan
International Regulatory Affairs Manager
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K972626
Trade Name: ADVANCE® Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: July 11, 1997
Received: July 14, 1997

Dear Mr. Regan:

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.

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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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. **Indications for Use of the Device**

510(k) Number (if known): K972626

Device Name: ADVANCE® Total Knee System Tibial Insert and Femoral Component

Indications for Use:

The ADVANCE® Total Knee System components are indicated for use in total 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.

These products are for use with cement only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **Or** **Over-the-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972626