

JAN 30 1998



WRIGHT

MEDICAL TECHNOLOGY, INC.

5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K974328

Contact Person: Kim Tompkins
Date: November 17, 1997

510(k) Summary

Trade Name: ADVANCE® Total Knee System, All Polyethelene Tibial Component, size 8mm
Common Name: Tibial Component
Classification: Class II
Predicate Device: ADVANCE® Total Knee System All Polyethylene Tibial Components manufactured by Wright Medical Technology, Inc.

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 All Polyethylene Tibial Component, size 8mm, is manufactured from ultra high molecular weight polyethylene. The device features cement pockets on the underside of the component. The device is designed to be used with bone cement.

This device is 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.

Testing

Submitted testing indicates that the device should withstand a load of 450 lbs for at least 10 million cycles. Additional testing indicates that no areas of unacceptable high stress were identified. Finally, testing provided indicates that the device provides adequate constraint for expected physiological loads.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Ms. Kim Tompkins
Director, Clinical and Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K974328
ADVANCE® Total Knee System, 8mm All
Polyethylene Tibial Component
Regulatory Class: II
Product Code: JWH
Dated: November 17, 1997
Received: November 18, 1997

Dear Ms. Tompkins:

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial component available is the nominal "8mm" sized component, which has a minimum polyethylene thickness under the condyles of 8.0mm.
2. This device may not be labeled or promoted for non-cemented use.
3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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.

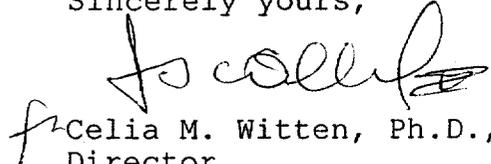
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,


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

Page 1 of 1

510(k) Number (if known): K974328

Device Name: ADVANCE Total Knee System, product line addition to include the 8mm thick all poly tibial component

Indications for Use:

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.

This device is intended for use with bone cement.

(Please do not write below this line—continue on another page if needed)

* * * * *

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)

[Signature]

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K974328

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