SUMMARY OF SAFETY AND EFFECTIVENESS:

This safety and effectiveness summary for the Ortho Development Balanced Knee™ System is provided as required per Section 513(i)(3) of the Food, Drug, and Cosmetic Act.

1. **Submitter:**
   Ortho Development Corporation
   106 West 12200 South
   Draper, Utah 84020

2. **Contact Person:**
   Carol Freasier
   Telephone: (801) 553-9991
   Fax: (801) 553-9993

3. **Trade Name:** Ortho Development Balanced Knee™ System
   Common Name: Balanced Knee™ System
   Classification Name: Prosthesis, Knee patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer (888.3560)

4. **Predicate or legally marketed devices which are substantially equivalent:**
   - Performance Total Knee System (Kirschner)
   - NexGen Total Knee System (Zimmer)
   - PCA Modular Total Knee System (Howmedica)
   - Natural Knee System (Intermedics)
   - AGC Modular Total Knee System (Biomet)
   - Foundation Total Knee System (Encore)

5. **Description of the device:**
   The Ortho Development Balanced Knee™ System is a semi-constrained total knee replacement system, consisting of femoral, tibial and patellar components.

   Materials: The devices are manufactured from CoCr alloy (cast or Wrought), Ti-6Al-4V alloy and Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM standards.

   Function: The system functions to provide restoration of function as a replacement for diseased and arthritic knees.

6. **Intended Use:**
   The Ortho Development Balanced Knee™ System is indicated for patients suffering from severe knee pain and disability. Specific indications include femoral, tibial and patellar replacement due to degenerative bone disease such as rheumatoid arthritis or osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyles, pseudo-gout, or complications from a previous prosthesis. This device is intended for cemented use only.

7. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
   There are no significant differences between the Ortho Development Balanced Knee™ System and the systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2000

Ms. Carol Freasier
Regulatory Affairs / Quality Assurance
Ortho Development Corporation
106 West 12200 South
Draper, Utah 84020

Re: K994370
Trade Name: Ortho Development Balanced Knee™ System
Regulatory Class: II
Product Code: JWH
Dated: December 23, 1999
Received: December 27, 1999

Dear Ms. Freasier:

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 control provisions of the Act. The general control 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.

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 at (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

510(k) Number (if known): K994370

Device Name: Balanced Knee™ System

Indications for Use

The Balanced Knee™ System is intended for single use in primary total knee replacement only. Indications include:

- Loss of joint configuration and joint function;
- Osteoarthritis of the knee joint;
- Rheumatoid arthritis of the knee joint;
- Post-traumatic arthritis of the knee joint;
- Moderate valgus, varus, or flexion deformities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994370

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)