SUMMARY OF SAFETY AND EFFECTIVENESS:

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

1. **Submitter:**
   Ortho Development Corporation
   12187 South Business Park Dr.
   Draper, Utah 84020

2. **Contact Person:**
   Nadeem Ahmed
   Telephone: (801) 553-9991
   Fax: (801) 553-9993

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

4. **Predicate or legally marketed devices which are substantially equivalent:**
   - PFC Sigma Total Knee System (DePuy)
   - Duracon Total Knee System (Howmedica)
   - Foundation Total Knee System (Encore)

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

   Materials: The devices are manufactured from Ti-6Al-4V alloy 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™ Modular Tibial 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™ Modular Tibial 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

JUL 15 2003

Mr. Nadeem Ahmed
Regulatory Affairs Manager
Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

Re: K031201
Trade/Device Name: Balanced Knee™ Modular Tibial System
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: April 14, 2003
Received: April 16, 2003

Dear Mr. Ahmed:

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.

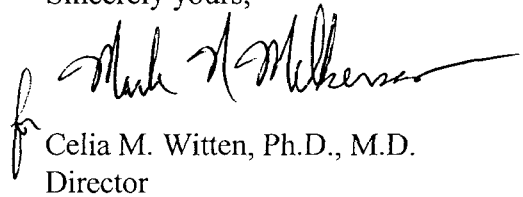
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

510(k) Number : ~~K(Pending)~~ K031201

Device Name: Balanced Knee™ Modular Tibial System

INDICATIONS FOR USE

The Balanced Knee™ Tibial Tray Pegged 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;
- Revision procedures where other treatments or devices have failed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K031201

Prescription Use _____ OR Over-The- Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)