SUMMARY OF SAFETY AND EFFECTIVENESS:

This safety and effectiveness summary for the Ortho Development Balanced Knee™ Tibial Tray Pegged 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 Drive
   Draper, Utah 84020

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

3. **Date Prepared:**
   February 4, 2002

4. **Name of the Device**

Trade Name:	Ortho Development Balanced Knee™ Tibial Tray Pegged
Proprietary Name:	Balanced Knee™ Tibial Tray Pegged
Common Name:	Balanced Knee™ Tibial Tray Pegged
Classification Name:	Prosthesis, Knee patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer
Reference:	(888.3560)

5. **Predicate or legally marketed devices which are substantially equivalent:**
   - Balanced Knee™ System (Ortho Development)
   - Natural Knee System (Intermedics Orthopedics)
   - Ortholoc Advantim System (Wright Medical)
   - Consensus Knee System (Hayes Medical)

6. **Description of the device:**
   The Ortho Development Balanced Knee™ Tibial Tray Pegged serves as an additional option to the tibial tray configurations currently offered in the Ortho Development Balanced Knee™ System, K994370, which include the tibial tray nonporous and the tibial tray porous.

   Materials: The devices are manufactured from forged Ti-6Al-4V ELI alloy and coated with CP Titanium per ASTM standards.

   Function: The Tibial Tray Pegged functions to provide restoration of function as a replacement for diseased and arthritic knees as part of the Ortho Development Balanced Knee™ System.

7. **Intended Use:**
   The Ortho Development Balanced Knee™ Tibial Tray Pegged 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.

8. Comparison of the technological characteristics of the device to predicate and legally marketed Ortho Development Balanced Knee™ System:

There are no significant differences between the Ortho Development Balanced Knee™ Tibial Tray Pegged and the Ortho Development Balanced Knee™ System currently being marketed which would adversely affect the use of the product. It is substantially equivalent to this device in design, function, material and intended use.

Parameter	Identical, Similar or Different	Similarities and Differences
Design	Identical Identical Identical Similar	• Both the predicate and the proposed devices have the same profile and keel geometry. • Both the predicate and the proposed devices incorporate the same locking mechanism to secure the UHMWPE insert. • Both the predicate and the proposed devices have the same surface finish specifications. • The proposed devices has pegs on the distal surface in place of screws on the tibial tray porous.
Materials	Identical Identical	• Ti-6Al-4V ELI Alloy for both the predicate and the proposed devices. • Porous coating for both the predicate and the proposed devices.
Manufacturing Process	Identical Identical	• Both the predicate and the proposed devices are machined from near net forgings. • Both the predicate and the proposed devices are porous coated using the same material specification and process.
Biocompatibility	Identical	• The materials used meet or exceed ASTM standards, are common to orthopedic products today, and leave an extensive safe clinical history.
Pyrogenicity	Identical	• Neither the predicate or the proposed devices are labeled as nonpyrogenic, Per USP XXII, NF18 (1995 edition), page 1719, "These requirements do not apply to orthopedic products."
Sterility	Identical	• Both the predicate and the proposed devices are terminally sterilized by gamma radiation. Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. The products are accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better (ANSI/AAMI/ISO 11137-1994, ANSI/AAMI ST32-1991 and ISO/TR 13409-1996)

9. Non-clinical Performance and Conclusions:

Addressed in the Ortho Development Balanced Knee™ System, K994370

10. Clinical Performance and Conclusions:

Clinical data and conclusion were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Ms. Carol Freasier
Regulatory Affairs/Quality Assurance
Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

Re: K020383
Trade/Device Name: Ortho Development Balanced Knee™ Tibial Tray Pegged
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 4, 2002
Received: February 5, 2002

Dear Ms. Freasier:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N. Melkerson

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 (if known): K020383 page 1 of 1

Device Name: Balanced Knee™ Tibial Tray Pegged

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.

The Ortho Development Balanced Knee™ Tibial Tray Pegged 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.

(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 K020383

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