K090705

OCT - 9 2009

ORTHO DEVELOPMENT
engineering simplicity

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:

Submitter:

Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

Contact Person:

Johanne Young
Manger, Quality Assurance and Regulatory/Clinical Affairs
Telephone: (801) 619-3450
Fax: (801) 619-8950

Date Prepared:

October 5, 2009

Name of the Device

Trade Name:	Balanced Knee System® Ultracongruent Tibial Insert
Common Name:	Knee Joint Prosthesis
Classification Name:	Prosthesis, Knee patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer (888.3560)
Product Code:	JWH

Predicate or legally marketed devices which are substantially equivalent:

- Ortho Development Corporation Balanced Knee System CR or PS Insert (K994770)
- Depuy Sigma Deep Dish Insert (K033272)
- Depuy LCS Deep Dish Bearing (P830055)
- Encore Medical Foundation Ultracongruent Insert (K923277)
- Hayes Medical Concensus Ultracongruent Insert (K001456)
- OMNI Life Science Apex Knee Ultracongruent Insert (K001456)
- Smith & Nephew Genesis II Dished Insert (K951987)
- Smith & Nephew (Plus Orthopedics) TC-PLUS Solution Ultracongruent Insert (K000666)
- Zimmer Insall-Bernstein PSCK Tibial Insert (K872379)
- Zimmer (Intermedics) Natural Knee II Ultracongruent and PS Insert (K912663, K936159)

Description of the device:

The Balanced Knee® System Ultracongruent Tibial Insert may be used in conjunction with the Balanced Knee System CR femorals, standard and modular tibial trays, tibial augments, stems, and patellae. The Ultracongruent Tibial Insert has an anterior lip and tighter anterior curvature to stabilize the knee in the anterior direction and are snap fitted into the tibial trays and locked in place by mating features, the circumferential rim of the tray, and tabs on the anterior and posterior sides. The Ultracongruent Tibial Insert is available in seven sizes to fit the majority of patients encountered. The sizes match each size of the Balanced Knee System tibial trays cleared under Premarket Notifications K994370, K020383, and K031201. The insert is symmetric, not left/right specific. It is supplied in thicknesses of 7, 8, 9, 10, 11, 12, 13, 14, 16, 18, and 20mm.

Materials: The device is manufactured from Compression Molded Ultra High Molecular Weight Polyethylene (UHMWPE, ASTM F-648).

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

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:

1. Loss of joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities.
6. Revision procedures where other treatments or devices have failed.

The Balanced Knee® System is indicated in the salvage of previously failed surgical attempts where femoral bone loss does not require the use of augments or stem extensions and where collateral ligaments may be relied upon for medial/lateral (M/L) stability.

Performance Testing:

The Food and Drug Administration have established no performance standards applicable to the Ultracongruent Tibial Insert, however biomechanical testing and analysis of the device was performed with results included as part of the submission. Clinical data and conclusion were not needed for this device.

Basis for substantial equivalency:

There are no significant differences between the components of the Ortho Development Ultracongruent Tibial Insert and other commercially available tibial inserts listed in the substantial equivalency section currently being marketed, which would adversely affect the use of the product. Testing met all acceptance criteria and verifies that the performance of the Ultracongruent Tibial Insert is substantially equivalent in design, function, material and intended use to the predicate devices.

INTENDED USE/INDICATIONS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ortho Development Corporation
% Ms. Johanne Young
Manager, Quality Assurance & Regulatory/Clinical Affairs
12187 South Business Park Drive
Draper, Utah 84020

OCT - 9 2009

Re: K090705
Trade Name: Balanced Knee System Ultracongruent Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: August 20, 2009
Received: August 21, 2009

Dear Ms. Young:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

Indications for Use of Device Form

510(k) Number (if known): K090705

Device Name: Balanced Knee® System Ultracongruent Tibial Insert

Indications for 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:

1. Loss of joint configuration and joint function.
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Prescription Use _____X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090705