K103837

MAR 2 4 2011

510(k) Summary

NAME OF SPONSOR:

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

510(k) CONTACT:

Tom Haueter
Regulatory Affairs Manager
Telephone: (801) 553-9991
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DATE PREPARED:

December 22, 2010

PROPRIETARY NAME:

Balanced Knee System Revision Offset Tibia

COMMON NAME:

Offset Tibial Tray Prosthesis

CLASSIFICATION:

21 CFR 888.3560, Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis, Class II device

DEVICE PRODUCT CODE:

JWH

PREDICATE DEVICES:

Balanced Knee Modular Tibial System (K031201)
Ortho Development Corp.

Offset Tibial Tray (K010212)
Biomet

Revision Knee System (K043440)
Smith & Nephew

Device Description

The proposed Balanced Knee System Revision Offset Tibia is a modular system intended for primary and revision knee surgery. It consists of an offset tibial tray, adapter, screw, and stem. All components are machined from titanium alloy (Ti-6Al-4V ELI).

Mechanical testing shows that the Balanced Knee System Revision Offset Tibia can withstand anticipated in vivo loading and cycling.

The Balanced Knee System revision Offset Tibia is an addition to the Balanced Knee System. The Balanced Knee System is comprised of:

Balanced Knee System (K994370)

Balanced Knee System Revision (K060569)

Balanced Knee Modular Tibial System (K031201)

Balanced Knee Tibial Tray Pegged (K020383)

BKS Ultra Congruent (K090705)

Intended Use

The Balanced Knee System Revision Offset Tibia is intended for use with the Balanced Knee System in total knee arthroplasty procedures, previously failed surgical attempts where bone loss may require the use of augments or stem extensions, or difficult primary surgical cases where a long extension stem is necessary.

Indications for Use

The Balanced Knee System is indicated for use in total knee arthroplasty procedures, for cemented use only.

Total knee arthroplasty is indicated for the following conditions:

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.

Basis for Substantial Equivalence

Ortho Development believes that the Balanced Knee System Revision Offset Tibia is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, and mechanical performance. The Tests for substantial equivalence include Tibial Tray fatigue and progressive static load mechanical tests, as well as assembly and disassembly tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ortho Development Corporation
% Mr. Tom Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

MAR 2 4 2011

Re: K103837
Trade/Device Name: Balanced Knee System Revision Offset Tibia
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-contrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 22, 2010
Received: December 30, 2010

Dear Mr. Haueter:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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,

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

Enclosure

Indication for Use Form
Ortho Development
Balanced Knee System Revision
Offset Tibia 510(k)

510(k) Number (if known): K103837

Device Name: Balanced Knee System Revision Offset Tibia

Indications for Use:

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Device Evaluation (ODE)

for M. Melkerson

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

510(k) Number K103837