



Food and Drug Administration  
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Ortho Development Corporation  
Mr. Drew Weaver  
Director of Regulatory Affairs and Quality Assurance  
12187 South Business Park Drive  
Draper, Utah 84020

October 27, 2015

Re: K152169

Trade/Device Name: Balanced Knee<sup>®</sup> System Trimax<sup>™</sup> CR Femoral Component and  
E-Vitalize<sup>®</sup> CR and UC Tibial Inserts

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, OIY

Dated: July 31, 2015

Received: August 4, 2015

Dear Mr. Weaver:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S**

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

Enclosure

## Indications for Use

510(k) Number (if known) K152169

Device Name

Balanced Knee® System TriMax™ CR Femoral Component and E-Vitalize® CR and UC Tibial Inserts

Indications for Use (Describe)

The Balanced Knee® System TriMax™ CR Femoral Component and E-Vitalize® CR and UC Tibial Inserts are intended for single use cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee 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 of the knee joint.
6. Revision procedures where other treatments or devices have failed.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## Section 5

### 510(k) Summary

**NAME OF SPONSOR:** Ortho Development Corporation  
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 Draper, Utah 84020

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**DATE PREPARED:** July 31, 2015

**PROPRIETARY NAME:** Balanced Knee® System TriMax™ CR Femoral Component and E-Vitalize® CR and UC Tibial Inserts

**COMMON NAME:** Total Knee Replacement Prosthesis

**CLASSIFICATION:** Class II Device

**PRODUCT CODES/REGULATION DESCRIPTION AND NUMBER:**  
 JWH - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)  
 OIY - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)

**PREDICATE DEVICES:**  
 Balanced Knee® System (K994370),  
*Ortho Development Corporation*  
 Balanced Knee® System Ultracongruent Tibial Insert (K090705),  
*Ortho Development Corporation*  
 Balanced Knee® System High Flex PS (K123457),  
*Ortho Development Corporation*  
 Balanced Knee® System High Flex Vitamin E PS Tibial Insert and Patella (K131337),  
*Ortho Development Corporation*

## Device Description

The Balanced Knee® System TriMax™ CR femoral component is a highly polished Co-Cr-Mo cruciate retaining femoral component that is designed to accommodate increased range of motion up to 150° of flexion. E-Vitalize® CR and UC tibial inserts are machined from extensively crosslinked, compression molded, Vitamin E UHMWPE (same material as K131337). All components are single use only and the TriMax™ CR femoral component is intended for cemented use only.

The E-Vitalize® CR and UC tibial inserts may be used with TriMax™ CR or BKS CR femoral components. E-Vitalize® CR and UC tibial inserts may also be used with all Ortho Development's tibial tray component offerings. The TriMax™ CR femoral component may be used with all Ortho Development patella component offerings.

## Intended Use

The Balanced Knee® System TriMax™ CR Femoral Component and E-Vitalize® CR and UC Tibial Inserts are intended for single use cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee 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 of the knee joint.
6. Revision procedures where other treatments or devices have failed.

## Technological Characteristics

The predicate devices and TriMax™ CR femoral component and E-Vitalize® CR and UC tibial inserts are based on the following same technological elements:

### TriMax™ CR Femoral Component

- Cruciate retaining femoral component design
- Increased range of motion up to 150° flexion
- Cemented fixation of femoral component onto prepared distal femur
- Available in a range of sizes to accommodate patient anatomy
- Material: Co-Cr-Mo ASTM F75-12

### E-Vitalize® CR Tibial Insert

- Cruciate retaining bearing surface design
- Available in a range of sizes and thicknesses to accommodate patient anatomy
- Use of a locking mechanism to secure tibial insert to tibial tray
- Material: Extensively Crosslinked Vitamin E Polyethylene UHMWPE ( $\alpha$ -tocopherol) ASTM F2695-12

## E-Vitalize® UC Tibial Insert

- Ultracongruent bearing surface design
- Available in a range of sizes and thicknesses to accommodate patient anatomy
- Use of a locking mechanism to secure tibial insert to tibial tray
- Material: Extensively Crosslinked Vitamin E Polyethylene UHMWPE ( $\alpha$ -tocopherol) ASTM F2695-12 (same material as K131337)

## Performance Data

The following non-clinical evaluations were performed and demonstrated substantial equivalence to the predicate devices: Range of Motion, Femorotibial Constraint, Femorotibial Contact Area, Patellofemoral Constraint, Patellofemoral Contact Area, Femoral Component Fatigue Strength, Insert Assembly/Disassembly, and Knee Wear.

## Basis for Substantial Equivalence

The TriMax™ CR femoral component and E-Vitalize® CR and UC tibial inserts are substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, and mechanical performance.