



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

United Orthopedic Corporation
Karen Ho
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu, 300
TAIWAN

April 12, 2016

Re: K152430

Trade/Device Name: All Poly Tibial Component

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: March 14, 2016

Received: March 17, 2016

Dear Ms. Ho:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)
K152430

Device Name
All Poly Tibial Component

Indications for Use (Describe)

The device is indicated for use in total knee arthroplasty in skeletally mature patients with the following conditions:

1. Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
2. Collagen disorders, and/or avascular necrosis of the femoral condyle.
3. Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
4. Moderate valgus, varus, or flexion deformities.
5. The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

The device includes Cruciate Retained (CR) type, Posterior Stabilized (PS) type and Ultracongruent (UC) type. CR and UC types are designed to collocate with CR femoral component, while PS type is designed to collocate with PS femoral component.

This device is a single use implant and intended for cemented use only.

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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510(k) Summary of Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
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Phone Number	+886-3-5773351 ext. 2212
Fax Number	+886-3-577156
Name of Contact Person	Karen Ho
	Regulation and Document Management
Date prepared	March 10, 2016

Name of Device

Trade Name	All Poly Tibial Component
Common Name	Total Knee Prosthesis

Regulation Name and Number

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis under 21CFR §888.3560

Device Class

Class II

Classification Panel

Orthopaedics

Product Code

JWH

Predicate Device

1. "OSTEONICS" Osteonics® Scorpio™ Posterior Cruciate Retaining Total Knee System (K974556)
2. "OSTEONICS" Osteonics® Scorpio™ Posteriorly Stabilized Total Knee System (K962152)
3. "UNITED" U2 Total Knee System (K051640, K131864)
4. "UNITED" Ultracongruent Insert (K132752)

Device Description:

All Poly Tibial Components are made of Ultra High Molecular Weight Polyethylene



(UHMWPE), including Cruciate Retained (CR) type, Posterior Stabilized (PS) type and Ultracongruent (UC) type. All types are available in sizes #0~#7 (ranging from 39.5mm/60mm AP/ML to 58mm/84mm AP/ML) with ten thickness options (9mm, 10mm, 11mm, 12mm, 13mm, 14mm, 15mm, 16mm, 17mm and 18mm). The CR type of All Poly Tibial Component is intended to accommodate the posterior cruciate ligament (PCL) if it is present. The PS type and UC type are intended to be used in situation where the posterior cruciate ligament is absent or cannot be preserved. All Poly Tibial Components can be used with femoral components of U2 Total Knee System and patella (K021657, K103733, K051640 and K082469) in primary or revision total knee arthroplasty. CR and UC types are designed to collocate with CR femoral component (K140073, K150829, K140075 and K150832) while PS type is designed to collocate with PS femoral component (K051640, K120507 and K150829). The X-ray marking wire which is made of Co-20Cr-15W-10Ni alloy is embedded in the All Poly Tibial Component for X-ray image identification purpose.

Indications for Use:

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2. Collagen disorders, and/or avascular necrosis of the femoral condyle.
3. Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
4. Moderate valgus, varus, or flexion deformities.
5. The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

The device includes Cruciate Retained (CR) type, Posterior Stabilized (PS) type and Ultracongruent (UC) type. CR and UC types are designed to collocate with CR femoral component, while PS type is designed to collocate with PS femoral component.

This device is a single use implant and intended for cemented use only.

**Comparison to Predicate Device:**

All Poly Tibial Component has the same basic design, intended use and materials as the device, “Osteonics” All-Polyethylene Tibial Component of Osteonics® Scorpio™ Posterior Cruciate Retaining Total Knee System (K974556) and Osteonics® Scorpio™ Posteriorly Stabilized Total Knee System (K962152). The differences between the subject and the predicate devices are the size distribution and sterilization method. However, the performance evaluation of the subject device was conducted and would not post issues about safety and effectiveness. Thus, we believe that the subjected All Poly Tibial Component is substantially equivalent to the predicate device.

Performance Data:**● Non-clinical Performance**

This 510(k) submission was prepared in accordance with the Agency's, " *Class II Special Controls Guidance Document: Knee Joint Patellofemoral and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA*". Tests as follows were conducted to evaluate the safety and effectiveness of the subject device, and the test results demonstrated the subject device is substantially equivalent to the predicate device.

- a. Range of Motion
- b. Contact Area and Contact Pressure
- c. Constraint Test
- d. Wear Simulation Test
- e. Fatigue Test

● Clinical Performance Data/Information

None provided as a basis for substantial equivalence.