DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 1, 2017

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

Re: K161360
Trade/Device Name: U2 Total Knee System, PSA Tibial Insert
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: December 13, 2016
Received: December 14, 2016

Dear Karen 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 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 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" (21 CFR 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161360

Device Name
U2 Total Knee System - PSA Tibial Insert

Indications for Use *(Describe)*
This device is indicated in knee arthroplasty in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require increased stabilization for tibiofemoral joint due to soft tissue imbalance. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.
Note: In the US, this device is 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	May 12, 2016

Name of Device

Trade Name	U2 Total Knee System – PSA Tibial Insert
Common Name	Tibial Insert

Regulation Name and Number	The device classification for **U2 Total Knee System - PSA Tibial Insert** is "Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis" and is contained in the Code of Federal Regulation, under **21CFR 888.3560**. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	JWH
Predicate Device	1. "UNITED" U2 Total Knee System – PSA Type (K082424) 2. "UNITED" U2 XPE Total Knee System (K103733)

Device Description:

U2 Total Knee System – PSA Tibial Insert is an extended design of U2 Total Knee System – PSA Type (K082424) including XPE Tibal Insert, PSA and XPE Tibial Insert,

PSA, LC. This System is a patellofemorotibial polymer / metal / polymer, semi-constrained, cemented knee prosthesis, which is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock. U2 Total Knee System – PSA Tibial Inserts are available in a range of thicknesses and in two design configurations: PSA and PSA–LC type. For the PSA tibial insert, it is intended for use in patients who require constrained stabilization for tibiofemoral joint due to soft tissue imbalance. PSA-LC (low constrained) tibial insert provide less constrained stabilization than PSA tibial insert.

Indications for Use:

This device is indicated in knee arthroplasty in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral joint surface erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require increased stabilization for tibiofemoral joint due to soft tissue imbalance. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

Note: In the US, this device is for cemented use only.

Comparison to Predicate Device:

U2 Total Knee System – PSA Tibial Insert has the same basic design, intended use, materials, locking mechanism and sterilization as the predicate devices, U2 Total Knee System – PSA Type (K082424) and U2 XPE Total Knee System (K103733). The only difference between the subject and the predicate devices is the profile design of the spine. 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 U2 Total Knee System – PSA Tibial Insert is substantially equivalent to the predicate device.

Performance Data:

- **Non-clinical Performance**

  Range of Motion and Spine Fatigue Test were conducted to evaluate the safety and effectiveness of the subjected device.

  The subject U2 Total Knee System – PSA Tibial Insert has the same curvature design at the articular surface as U2 Total Knee system – PSA Type which was previously cleared by FDA (K082424). Thus, the constraint, contact area and contact pressure of the subject PSA Tibial Insert should be identical with U2 Total Knee system – PSA Type (K082424). In addition, the material, size distribution and the locking mechanism of the subject PSA-LC Tibial Insert is identical to the on-marketed PSA insert (K082424). The wear performance could be represented by the on-marketed U2 XPE Tibial Insert (K103733) due to the same contact area and size distribution.

  Bacterial endotoxin testing was conducted and met the endotoxin limit as specified in USP <161>.

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.