September 23, 2019

United Orthopedic Corporation
Lois Ho
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu, 30075
TAIWAN

Re: K190100
Trade/Device Name: USTAR II System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, LPH, LWJ, KWL
Dated: August 14, 2019
Received: August 22, 2019

Dear Lois 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190100

Device Name
USTAR II System

Indications for Use *(Describe)*

USTAR II Knee System

1. Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed.
2. Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
3. Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
4. Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis.
5. Joint instability resulting from excessive bone resection.

For Femoral component, Hinged/ Tibial baseplate, Hinged/ Cemented tibial stem/ Cemented Straight stem, RHS, non coated/ Cemented Curved stem, RHS, non coated/ Cemented Straight stem, RHS/ Cemented Curved stem, RHS/ Tibial Augment: These devices are single use implant and intended for cemented use only.

For Distal Femoral Component, RHS/ Proximal Tibial Component, RHS/ Tibial stem/ Segment Part, RHS/ Segment Part, RHS, Bridge: These devices are single use implant and intended for cementless use only.

USTAR II Knee System, Stem

1. Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) resulting from trauma where massive resection and transplantation are needed.
2. Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
3. Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
4. Correction for revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement.
5. Joint instability resulting from excessive bone resection.

Cemented Tibial Stem is a single use implant and intended for cemented use only.
Tibial Stem is a single use implant and intended for cementless use only.

USTAR II Hip System

1. Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed.
2. Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
3. Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
4. Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis.
5. Joint instability resulting from excessive bone resection.

This device is a single use implant and intended for cementless 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of K190100

Submitter Information	
Name	United Orthopedic Corporation
Address	No.57, Park Ave. 2, Science Park, Hsinchu City 30075, Taiwan.
Phone Number	+886-3-5773351 ext. 2220
Fax Number	+886-3-577156
Name of Contact Person	Lois Ho, Regulatory Affairs Manager
Date prepared	January 08, 2019
Device Information	
Trade Name	USTAR II System
Common Name	Total Knee Prosthesis / Total Hip Prosthesis
Classification Panel	Orthopedics
Regulation Name and Number	Knee joint femorotibial metal/polymer constrained cemented prosthesis (21CFR 888.3510**);** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)
Regulatory Class	Class II
Product Code(s)	KRO, LPH, LWJ, KWL
Predicate Device(s)	1. “United” U2 Total Knee System – PSA Type (K082424, K100981, K122183) 2. “Zimmer” NexGen® Complete Knee Solution Rotating Hinge Knee (K013385) 3. “Zimmer” Zimmer® Segmental System (K070978, K110940)

	4. “Biomet” Orthopaedic Salvage System (K002757, K052685) 5. “Zimmer” Arcos Modular Femoral Revision System (K130063)
Reference Device(s)	1. “United” UTF Stem, reduced, Ti plasma spray (K123550) 2. “United” UCP Stem (K152530) 3. “United” U2 Hip stem, cemented (K111546) 4. “Stryker” Global Modular Replacement System (K023087) 5. “Zimmer” Vanguard™ DCM tibial insert (K100048)

Device Description:

"United" USTAR II System is used for patients who need a special prosthesis for their particular indication, which may present large quantity of bone loss and deformity associated with previous failed arthroplasty, ligament deficiencies, one tumors resection, or trauma and may require a further operation or reconstruction.

USTAR II System includes two sub-systems, which is "**USTAR II Knee System**" and "**USTAR II Hip System**". USTAR II Knee System is designed as modular combinations. It offers a variety of component options for treatment of patients that require femoral component, tibial baseplate and tibial insert. The tibial augment, segment part and stem are provided for patient with more bone resection. USTAR II Hip System is designed as a modular system which is composed Proximal femoral component, Trochanteric claw, and Press-fit, RHS straight/curved stem.

Indications for Use:

USTAR II Knee System

Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed.

Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.

Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.

Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis.

Joint instability resulting from excessive bone resection.

For Femoral component, Hinged/ Tibial baseplate, Hinged/ Cemented tibial stem/ Cemented Straight stem, RHS, non coated/ Cemented Curved stem, RHS, non coated/ Cemented Straight stem, RHS/ Cemented Curved stem, RHS/ Tibial Augment: These

devices are single use implant and intended for cemented use only.

For Distal Femoral Component, RHS/ Proximal Tibial Component, RHS/ Tibial stem/ Segment Part, RHS/ Segment Part, RHS, Bridge: These devices are single use implant and intended for cementless use only.

USTAR II Knee System, Stem

Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) resulting from trauma where massive resection and transplantation are needed.
Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
Correction for revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement.
Joint instability resulting from excessive bone resection.

Cemented Tibial Stem is a single use implant and intended for cemented use only.
Tibial Stem is a single use implant and intended for cementless use only.

USTAR II Hip System

Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed.
Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis.

Joint instability resulting from excessive bone resection.

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

Comparison of Technological Characteristics with the Predicate Device:

The features of the subject device are comparable to the predicates mentioned above in terms of the indication for use, design rationale, materials, coating and sterilization method. The differences have been validated by several testing to demonstrate that the performance of subject device is substantially equivalent to that of the predicate devices.

Performance Data:

- **Non-clinical Performance**

  Tests as follows were conducted to evaluate the safety and effectiveness of the subject device:

  a. Hyperextension fatigue test
  b. Internal and external rotation
  c. Wear and corrosion test
  d. Stem fatigue test
  e. Neck fatigue test
  f. Range of Motion
  g. Disassembly Force and Fretting Corrosion
  h. Evaluation of Modified Surface Treatment
  i. Bacterial endotoxin testing was conducted and met the endotoxin limit as specified in USP <161>.

  Performance data demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.

- **Substantial Equivalence Conclusion:**

  The subject device has the same intended use, materials, coating, sterilization method, and similar design features to the predicates mentioned above. The performance results demonstrate that the subject device is as safe and effective as the legally marketed predicate devices. Based on the information provided, “United” USTAR II System is considered substantially equivalence to that of predicate devices.