United Orthopedic Corporation
Gimpel Chien
Regulatory Affairs Manager
No. 57, Park Avenue 2, Science Park
Hsinchu, 300 Taiwan

October 24, 2017

Re: K172251
Trade/Device Name: UTS Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWY
Dated: July 21, 2017
Received: July 26, 2017

Dear Gimpel Chien:

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 (DICE) 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 (DICE) 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,

Laurence D. Coyne -S

For
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)*
K172251

Device Name
UTS Stem

Indications for Use *(Describe)*
This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions:
1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatments or devices have failed.
This device is designed for cementless use.

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 Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
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Fax Number	+886-3-5777156
Name of Contact Person	Gimpel Chien Regulation and Document Management
Date prepared	July 21, 2017

Name of Device

Trade Name	UTS Stem
Common Name	Hip Stem

Regulation Name and Number	The device classification for **UTS Stem** is "Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis." and is contained in the Code of Federal Regulation, under **21CFR 888.3358**. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	LPH, KWY, LZO
Predicate Device	1. "UNITED" UTF Stem (K110245) 2. "UNITED" UTF Stem, Reduced (K123550) 3. "UNITED" UTF Stem-reduced, Additional Sizes (K132207) 4. "UNITED" UTF Stem, reduced, #0, #00 (K163193) 5. Depuy Tri-lock Bone Preservation Stem (K073570)

UTS Stem *510(k) Summary*

Device Description:

UTS Stem is a modular, wedge-shaped stem with 12/14 neck taper and 130° neck angle, which is made from forging Ti-6Al-4V alloy (ASTM F136-13) and the proximal part of each femoral stem is coated with CP Ti powder (ASTM F1580-12) provides biological fixation. UTS Stem is available with standard offset and high offset to restore hip biomechanics. The standard offset is available in sizes #00~#14; the high offset is available in sizes #1~#14.

Indications for Use:

This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatments or devices have failed.

This device is designed for cementless use.

Comparison to Predicate Device:

The features of the subject device including indication for use, material, design rationale, size distribution and sterilization method are discussed in detail as follow to compare with the predicate devices:

1) Indication for use

UNITED UTS Stem is intended to use in total hip replacement or bipolar hip replacement, that is the same as the predicate UNITED UTF Stem-reduced (K123550, K132207,

K163193) and UNITED UTF Stem (K110245)

2) Material

The subject UTS Stems are made of Ti-6Al-4V alloy (ASTM F136-13) and plasma coated with CP Ti powder(ASTM F1580-12), which are identical to the predicate UNITED UTF Stem-reduced (K123550, K132207, K163193), UNITED UTF Stem (K110245).

3) Design rationale

The Subjects UTS Stems are Tri-tapered wedge design which is identical to the predicate "Depuy" Tri-lock Bone Preservation Stem (K073570).

4) Size

"UNITED" UTS Stem is an extension line of UTF reduced stem (K123550, K132207, K163193), and the mechanical properties including neck fatigue, stem fatigue and range of motion have been conducted to evaluate the safety and performance.

5) Sterilization method

The subject device is sterilized by Co-60 gamma radiation which is identical with the predicate devices (K110245, K123550, K132207, K163193, K073570).

The subject device is a extension line of the cleared "UNITED" UTF reduced stem (K123550, K132207 and K163193) and the mechanical properties including neck fatigue and stem fatigue have been conducted to evaluate the safe and performance and test results demonstrated that the subject device is as safe and effective as the predicates.

Performance Data:

- **Non-clinical Performance**

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

a. Stem Fatigue Test
b. Neck Fatigue Test
c. Range of Motion
d. Evaluation of disassembly force and fretting corrosion between femoral head and stem
e. Evaluation of Modified Surface Treatment
f. 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.