



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

United Orthopedic Corporation
Gimpel Chien
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu, 300 TW

June 8, 2017

Re: K163193

Trade/Device Name: UTF Stem, reduced, #0, #00

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, KQY, LZO

Dated: April 14, 2017

Received: April 17, 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 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,

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)

K163193

Device Name

UTF Stem, reduced, #0, #00

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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UTF Stem, reduced, #0, #00

510(k) Summary

510(k) Summary of Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
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Phone Number	+886-3-5773351 ext. 2217
Fax Number	+886-3-577156
Name of Contact Person	Gimpel Chien
	Regulation and Document Management
Date prepared	November 10, 2016

Name of Device

Trade Name	UTF Stem, reduced, #0, #00
Common Name	Hip Stem

Regulation Name and Number

The device classification for **UTF Stem, reduced, #0, #00** 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, Reduced (K123550)
 2. “UNITED” UTF Stem-reduced, Additional Sizes (K132207)
 3. “UNITED” UTF Stem (K110245)
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Device Description:

This subject device is a size extension of the cleared "UNITED" UTF Stem – reduced (K123550, K132207). The indications, materials, design of this subject device are identical to the cleared "UNITED" UTF Stem – reduced (K123550, K132207) except for size distribution. "UNITED" UTF Stem – reduced is a modular, wedge-shaped stem with 12/14 neck taper and 130° neck angle, which is indicated for use in primary or revision hip arthroplasty. UTF Stem – reduced is available with standard offset and high offset options to restore hip biomechanics.

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 subject device is a size extension to the cleared "UNITED" UTF Stem-Reduced (K123550, K132207). The indications, materials, design, manufacturing process of the subject device are identical to the cleared "UNITED" UTF Stem-Reduced (K123550, K132207). Besides, the indications, materials, manufacturing process of the subject device are identical to the cleared "UNITED" UTF Stem (K110245), except for the reduced distal width and the enlarged thread diameter of the impact hole. However, the design modifications do not change the intended use or fundamental scientific technology. The



subject device is smallest size option of UTF reduced stem 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. 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.
