DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

United Orthopedic Corporation
Ms. Karen Ho
Regulatory Affairs Manager
Number 57, Park Avenue 2, Science Park
Hsinchu 300
TAIWAN

March 14, 2016

Re: K152530
Trade/Device Name: UCP Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, LWJ, KWY
Dated: January 29, 2016
Received: February 1, 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

Indications for Use

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

510(k) Number *(if known)*
K152530

Device Name
UCP Stem

Indications for Use *(Describe)*

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.
4. Revision procedures where other treatments or devices have failed.
5. Patients suffering from disability due to previous fusion.
6. Patients with acute femoral neck fractures.

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.

UCP Stem *510(k) Summary*

510(k) Summary of Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
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Name of Contact Person	Karen Ho Regulation and Document Management
Date prepared	March 3, 2016

Name of Device

Trade Name	**UCP Stem**
Common Name	Hip Stem

Regulation Name and Number	The device classification for **UCP Stem** is: 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis; 21 CFR 888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis; 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. This falls under the Orthopedic Panel.
Device Class	Class II
Classification	Orthopedics
Product Code	LZO, JDI, LWJ, KWY
Predicate Device	1. "DePuy" DePuy C-Stem AMT (K082239) 2. "Zimmer" CPT® 12/14 Hip Prostheses (K030265)

Device Description:

UCP (United Cement Polished) stem is a triple tapered, polished, collarless stem. It is available for three series: Standards offset, High offset and Long stem to accommodate

various surgical requirements. UCP Stem is intended to be fixed only with the use of PMMA bone cement and should be used with centralizer and cement restrictor. UCP stem, centralizer and cement restrictor are made of Co-Cr-Mo alloy (ASTM F799-11), PMMA and UHMWPE (ASTM F648-14/ISO5834), respectively. UCP Stem is intended to use for primary or revision hip arthroplasty. For total hip arthroplasty, UCP Stem can be used with UNITED acetabular liner, cup and femoral head. For bipolar hip replacement, UCP Stem can be used with UNITED bipolar prosthesis.

Indications for Use:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.
4. Revision procedures where other treatments or devices have failed.
5. Patients suffering from disability due to previous fusion.
6. Patients with acute femoral neck fractures.

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

Comparison to Predicate Device:

From view of the material, design rationale, intended use and sterilization method, UCP Stem is substantial equivalent to the predicate devices. The difference between the subject and the predicate devices is size distribution. However, the stem length of UCP Stem is within the size range of the predicate devices. The difference of size distribution does not affect the intended use of the device or alter the fundamental scientific technology of the device. As a result, UCP Stem is substantially equivalent to the predicate devices.

Performance Data:

- **Non-clinical Performance**

Tests as follows were conducted to evaluate the safety and effectiveness of the subjected device, and the test results comply with the recommendations according to the FDA guidance "Guidance for Industry and FDA Staff: Non-clinical Information for Femoral Stem Protheses".

The following mechanical tests of the UCP Stem were performed:

a. Stem Fatigue Test
b. Neck Fatigue Test
c. Range of Motion
d. Mechanical Testing for Ceramic Femoral Head while Collocating with UCP Stem

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.