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
Gimpel Chien
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu 300
Taiwan

July 17, 2017

Re: K162957
Trade/Device Name: U2 Femoral Head
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
Dated: June 12, 2017
Received: June 13, 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

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)*

K162957

Device Name

U2 Femoral Head

Indications for Use *(Describe)*

The device is indicated for use in hip arthroplasty in patients with the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery.

This device is a single use implant and intended for cementless use only except cemented stem which is designed 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
Address	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
Phone Number	+886-3-5773351 ext. 2217
Fax Number	+886-3-577156
Name of Contact Person	Gimpel Chien Regulation and Document Management
Date prepared	July 14, 2016

Name of Device

Trade Name	U2 Femoral Head
Common Name	Femoral Head Prosthesis

Regulation Name and Number	The device classification for **U2 Femoral Head** 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
Predicate Device	1. "United" U1 Hip System (K994078) 2. "United" U2 Acetabular Cup and Femoral Head (K022520) 3. "United" U2 Hip System (K111546) 4."United" Femoral Heads, 2.5 and 7.5 mm Neck Length (K122504) 5."United" U2 Bipolar Implant and 22mm Femoral Head (K152439)

U2 Femoral Head *510(k) Summary*

Reference Device

1. "United" UTF Stem-reduced, Additional Sizes (K132207)
2. "United" U-Motion II PS+ Cup (K132455)
3. "United" U2 Hip Stem, Ti Porous Coated, Matrix (K151316)
4. "United" UCP Stem (K152530)

Device Description:

UNITED U2 femoral head is a modification of the cleared UNITED femoral head (K994078, K022520, K111546, K122504 and K152439) which is intended to use in primary or revision total/hemi hip arthroplasty. U2 femoral heads include three series of products: U2 Femoral head, U2 Femoral head, 3/4 polished and U2 Femoral head, 4/5 polished.

U2 femoral heads provide five different diameters of 22 mm, 26 mm, 28 mm, 32 mm and 36 mm. 22 mm is available in +0, +3, +6 and +9 mm of neck length, 26 mm is available in -2, +0, +3, +6 and +9 mm of neck length and 28 mm to 36 mm are available in -3, +0, +2.5, +5, +7.5 and +10 mm of neck length. A variety of diameters and neck lengths are available for various patient anatomies, adjustment of the tension of the ligaments, and reconstruction of the center of the physiological head of the femur.

U2 femoral heads is design for compatibility with various types of UNITED Hip Stem (K062978, K003237, K003237, K151316, K111546, K111546, K152530, K123550, K132207). For total hip replacement, U2 femoral heads can be used in conjunction with U2 Acetabular Cup Liner (K050262), XPE Cup Liner (K111546), U2 HA/Ti Plasma Spray Cup (K050262, K121777), U2 Ti Plasma Spray Cup (K050262, K121777), U2 Ti Porous Coated Cup (K111546) and U-Motion II Acetabular System (K122185, K132455). For hemi hip arthroplasty, U2 femoral heads can be used with U2 Bipolar Implant (K152439).

Indications for Use:

The device is indicated for use in hip arthroplasty in patients with the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery.

This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only.

Comparison to Predicate Device:

U2 Femoral Head has the same material, basic design, indications, dimension characteristic and sterilization method as the predicate devices, UNITED femoral heads (K994078, K022520, K111546, K122504 and K152439). The differences between the subject and the predicate devices are the chamfer design and the neck length. The chamfer design change would not affect the intended use and performance of the device. The mechanical performance of the subject device was analyzed and the result showed that these design features would not post issues about safety and effectiveness. Thus, we believe that the subjected U2 Femoral Head is substantially equivalent to the predicate device.

Performance Data:

- **Non-clinical Performance**

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

  a. Disassembly force between U2 femoral head and stem component
  b. Range of Motion
  c. 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.