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

April 7, 2016

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

Re: K152439
Trade/Device Name: U2 Bipolar Implant and 22mm Femoral Head
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: March 8, 2016
Received: March 11, 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

Indication for Use

510 (k) Number (if known): K152439

Device Name: **U2 Bipolar Implant and 22mm Femoral Head**

Indications for Use:

This device is intended for use in combination with UNITED Femoral System for cemented or cementless hip replacement. This device may be used for the following conditions:

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. Correction of function deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment of nonunion femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use __x__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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. 2212
Fax Number	+886-3-577156
Name of Contact Person	Karen Ho Regulation and Document Management
Date prepared	August 21, 2015

Name of Device

Trade Name	U2 Bipolar Implant and 22 mm Femoral Head
Common Name	Bipolar Implant and Femoral Head

Classification Name and Regulation	The device classification for **U2 Bipolar Implant and 22 mm Femoral Head** is "Hip Joint femoral (Hemi-Hip) Metal/Polymer Cemented or Uncemented Prosthesis " and is contained in the Code of Federal Regulation, under **21CFR 888.3390**. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	KWY
Predicate Device	1. "United" U2 Bipolar Implant (K101670) 2. "United" U1 Hip System-Bipolar (K050269) 3. "United" U1 Hip System--Femoral Head (K994078) 4. "Stryker" UHR Universal Head Bipolar System (K800207) 5. "Zimmer" VerSys Hip System--Femoral Head (K964769) 6. "Exactech" AcuMatch L-Series Bipolar Endoprosthesis (K013211) 7. "Aesculap" Aesculap BiPolar Acetabular Cup (K060707)

U2 Bipolar Implant and 22mm Femoral Head *510(k) Summary*

Device Description:

U2 Bipolar Implant

U2 Bipolar Implant is intraoperatively assembled to any appropriately size UNITED femoral stem with compatible head size. This device is offered in 38-56 mm outer diameters and with 22mm, 26mm and 28mm inner diameter. It is comprised of an outer shell (ASTM F75-12/ ISO 5832-4:2014 casting Co-Cr-Mo alloy, raw materials ASTM F1537-11/ISO 5832-12:2007) into a permanently assembled bearing insert (ASTM F648-14/ISO 5834-1:2005 and ISO 5834-2:2011). The minimum thickness of the polyethylene at the load bearing area is 5 mm. The assembled prosthesis provides for primary articulation at the femoral head/inner polyethylene bearing interface and secondary articulation at the outer shell/acetabulum interface. The internal aspect of the shell is designed to lock the polyethylene liner. The outer metal surface of the bipolar hip prosthesis is highly polished for articulation with the patient's acetabulum.

Femoral Head, 22mm

Femoral head for size 22mm is designed for use with U2 Bipolar Implant. It is made of Co-Cr-Mo alloy (ASTM F1537-11). The material and process method of 22 mm femoral head are identical to the previous cleared "United" femoral head (K994078).

Intended Use:

This device is intended for use in combination with UNITED Femoral System for cemented or cementless hip replacement. This device may be used for the following conditions:

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. Correction of function deformity.
4. Revision procedures where other treatments or devices have failed.

5. Treatment of nonunion femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Comparison to Predicate Device:

The subject device--U2 Bipolar Implant is identical to the cleared "United" U2 Bipolar Implant (K101670) except size distribution and the design of stopper ring. However, the size distribution is substantially equivalent to "Exactech" AcuMatch L-Series Bipolar Endoprosthesis (K013211), and the performance evaluation for stopper ring of subject device was also conducted. The differences between subject and predicate devices would not pose issues about safety and effectiveness.

Performance Data:

- **Non-clinical Performance**

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

a. Locking Mechanism of U2 Bipolar Implant
b. Range of Motion of U2 Bipolar Implant
c. Disassembly Force for Femoral Head and Stem

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.