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

August 13, 2015

United Orthopedic Corporation
Ms. Karen Ho
Regulatory Affairs Manager
57, Park Avenue 2, Science Park
Hsinchu, 300
Taiwan, Republic of China

Re: K151316
Trade/Device Name: U2 Hip Stem, Ti Porous Coated, Matrix
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: May 15, 2015
Received: May 18, 2015

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 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 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): K151316 (page 1 / 1)

Device Name: **U2 Hip Stem, Ti Porous Coated, Matrix**

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. 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 is unmanageable using other techniques.

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

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

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Name of Contact Person	Karen Ho Regulation and Document Management
Date prepared	May 15, 2015

Name of Device

Trade Name	**U2 Hip Stem, Ti Porous Coated, Matrix**
Common Name	Cementless Hip Stem

Classification Name and Regulation	The device classification for **U2 Hip Stem, Ti Porous Coated, Matrix** 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	The predicate device is the "UNITED" U2 Hip Stem, Ti Porous Coated (K003237)

Device Description:

The U2 Ti Porous Coated Matrix Stem is single use component intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. U2 Ti Porous Coated Matrix Stem, made from a Ti-6Al-4V alloy conforming to ASTM F136-13/ISO 5832-3:1996, is a modular stem with 12/14 neck taper and 130° neck angle.

U2 Hip Stem, Ti Porous Coated, Matrix *510(k) Summary*

The proximal part of each femoral stem is coated with porous coating in thickness 600±100 μm using -45+60 mesh of CP Ti powder (ASTM F1580-12). The bulleted geometry stem tip of U2 Ti Porous Coated Matrix Stem helps reduce distal point loading while creating a smooth transition zone for load transfer. This stem system is available in thirteen sizes. U2 Ti Porous Coated Matrix Stem can be used with U1, U2 Acetabular components (K994078, K050262, K121777, K111546), U-Motion II Acetabular System components (K122185, K132455) and UNITED Femoral Head (K994078, K022520, K122504, K103497, K111546, K112463, K122185) for total hip replacement. For hip hemi-arthroplasty, U2 Ti Porous Coated Matrix Stem can be used in conjunction with Bipolar products (K101670).

Intended 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. 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 is unmanageable using other techniques.

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 Hip Stem, Ti Porous Coated, Matrix is modification and an additional size extension U2 Hip Ti Porous Coated Stem which was previously cleared by FDA (K003237). The differences from the existing products include design change for porous-coated area, modifying stem tip from cylindrical to bulleted geometry and modifying impact hole.

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" and "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement".

  The following mechanical tests of the U2 Hip Ti Porous Coated Stem were performed:

a. Stem Fatigue Test with Torsion
b. Neck Fatigue Test with Torsion
c. Mechanical Properties of Titanium Porous Coating Surface

- **Clinical Performance Data/Information**

  None provided as a basis for substantial equivalence.