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. Gimpel Chien
Regulation and Document Management
No 57, Park Ave 2, Science Park
Hsinchu 300
Taiwan

August 25, 2017

Re: K163441
Trade/Device Name: Locking Cage, Full XPE Cup
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
Dated: July 31, 2017
Received: August 2, 2017

Dear Ms. 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)*
K163441

Device Name
Locking Cage, Full XPE Cup

Indications for Use *(Describe)*

For Locking Cage

1. Revision of previous unsuccessful acetabular replacement.
2. Class III segmental and/or cavitary acetabular defects which make it difficult to achieve satisfactory results while using standard total hip replacement acetabular components and procedures.

For Full XPE Cup

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, 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 and femoral neck fractures of the proximal femur with head involvement that is unmanageable using other techniques.

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.

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	August 18, 2017

Name of Device

Trade Name	Locking Cage, Full XPE Cup
Common Name	Acetabular component

Regulation Name and Number	The device classification for **Locking Cage, Full XPE Cup** are "prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented" and "prosthesis, hip, semi-constrained, metal/polymer, cemented" which are contained in the Code of Federal Regulation, under **21CFR 888.3353 and 21 CFR 888.3350**, respectively. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	LZO, JDI
Predicate Device	1. "Stryker Howmedica Osteonics" GAP-II Restoration Acetabular Shells (K980774) 2. "Smith & Nephew" Cemented all polyethylene Acetabular component (K991026) 3. "United" U-Motion II Acetabular Component (K122185)

4. "Howmedica" Trident® Crossfire® Polyethylene Liners (K021911)

Device Description:

"United" Locking Cage

The "United" Locking Cage is designed to achieve stable and lasting fixation of the severely deficient acetabulum. The "United" Locking Cage includes locking cage and several accessory components including: ischial flange, hook, cancellous locking screw and auto break-off locking nut. They are all manufactured from Ti6Al4V which confirms to ASTM F136-13.

"United" Full XPE Cup

The "United" Full XPE Cup is designed for cemented use and assembled with a PMMA Spacer and an X-ray marking wire. The Full XPE Cup is manufactured from highly cross-linked UHMWPE which conforms to ASTM F2565-06. The UHMWPE raw material is in accordance with ASTM F648-14 and ISO 5834-1:2005. The PMMA Spacer and X-ray marking wire are made of PMMA (Medical Grade) and Co-20Cr-15W-10Ni alloy (ASTM F90-14), respectively. The X-ray marking wire is designed for X-ray image identification purpose. The "United" Full XPE Cup is available in a range of sizes to fit varying anatomical requirements.

The "United" Locking Cage can be used with correspondent sizes of "United" Full XPE Cup with bone cement. The "United" Full XPE Cup is also compatible with "United" Metal Femoral Head (K994078, K022520, K111546 and K122504) and "United" Ceramic Femoral Head (K103497) in correspondent sizes. The "United" Femoral Heads can be used with various types of "United" hip stems (K003237, K062978, K111546, K123550, K132207, K151316 and K152530).

Indications for Use:

For Locking Cage

1. Revision of previous unsuccessful acetabular replacement.
2. Class III segmental and/or cavitary acetabular defects which make it difficult to achieve satisfactory results while using standard total hip replacement acetabular components and procedures.

For Full XPE Cup

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, 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 and femoral neck fractures of the proximal femur with head involvement that is unmanageable using other techniques.

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

Comparison to Predicate Device:

"United" Locking Cage

The "United" Locking Cage is substantially equivalent to "Stryker Howmedica Osteonics" GAP-II Restoration Acetabular Shells (K980774) in indications, design rationale, dimension characteristic and sterilization method.

"United" Full XPE Cup

The Full XPE Cup is substantially equivalent to "Smith & Nephew" REFLECTION cross-linked UHMWPE Acetabular Components (K991026) in indications, material, design rationale, dimension characteristic and sterilization method.

Performance Data:

- **Non-clinical Performance**

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

  a. Structural compression stiffness of locking cage
  b. ROM for Full XPE Cup
  c. Bending fatigue testing of flanges
  d. Locking strength of locking cage and cemented cup
  e. Endurance testing
  f. 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.