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

June 12, 2018

Re: K172833
Trade/Device Name: E-XPE Acetabular Components and U-Motion II Acetabular 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: OQI, LZO, MEH, JDI, LWJ, KWY
Dated: May 11, 2018
Received: May 14, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172833

Device Name
I) E-XPE Acetabular Components
II) U-Motion II Acetabular Cup

Indications for Use *(Describe)*

For E-XPE Cup Liner and U-Motion II Acetabular Cup

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Correction of functional deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture 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.

For E-XPE Cemented 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.

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510(k) Summary of Safety and Effectiveness

Submitter Information

Name	United Orthopedic Corporation
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Fax Number	+886-3-577156
Name of Contact Person	Gimpel Chien Regulation and Document Management
Date prepared	September 13, 2017

Name of Device

Trade Name	I) E-XPE Acetabular Components II) U-Motion II Acetabular Cup
Common name	Acetabular Component

Classification Name and Regulation

I) The device classification for **E-XPE Acetabular Components** is "Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis" and "Hip joint metal/polymer semi-constrained cemented prosthesis" which are contained in the Code of Federal Regulation, under **21CFR 888.3353** and **21CFR 888.3350**. This falls under the Orthopedic Panel.

II) The device classification for **U-Motion II Acetabular Cup** is "Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis" which is contained in the Code of Federal Regulation, under **21CFR 888.3353**. This falls under the Orthopedic Panel.

E-XPE Acetabular Components *510(k) Summary*

Device Class	Class II
Classification Panel	Orthopaedics
Product Code	I) **E-XPE Acetabular Components:** OQI, LZO, MEH, JDI II) **U-Motion II Cup:** LZO, LWJ, KWY, MEH
Predicate Device	1. "UNITED" U-Motion II Acetabular System (K122185) 2."Corin" Trinity Acetabular System ECIMA Liners (K111481) 3."Encore" X-alt™ Highly Cross Linked Acetabular Liner with Vitamin E (K130365) 4. "UNITED" Locking Cage, Full XPE Cup (K163441) 5. "UNITED" U2 Acetabular Component (K050262) 6. "UNITED" U2 Hip System (K111546)
Reference Device	"UNITED" UCP Stem (K152530)

Device Description:

For E-XPE Acetabular Components

The subject E-XPE Acetabular Components includes U-Motion II E-XPE Cup Liner and E-XPE Cemented Cup. U-Motion II E-XPE Cup Liner includes 0° and 20° hood designs, which are available in 28 mm, 32 mm, 36 mm and 40 mm inner diameter (ID). The 28 mm liners fit the acetabular cups with outer diameter (OD) ranging from 44-46 mm, the 32 mm liners fit the acetabular cups ranging from 46-50 mm, the 36 mm liners fit the acetabular cups ranging from 50-70 mm, and the 40 mm liners fit the acetabular cups ranging from 56-70 mm.

The E-XPE Cemented Cup is design for cemented use and assembled with a PMMA Spacer and an X-ray marking wire. The cement mantle is built within the outer surface of acetabular cup. The PMMA Spacer is designed for cement fixation with a uniform cement thickness and the X-ray marking wire is designed for X-ray image identification purpose. E-XPE Cemented Cups are available in a range of sizes to fit varying anatomical

requirements.

For U-Motion II Acetabular Cup

The indication for use, materials, cup hole types, size distribution, sterilization method, safety and effectiveness of subject device are identical to predicate device (K122185) except the locking design. The subject device are available in sizes from 44 mm through 80 mm outer diameter in 2 mm increments.

Intended Use:

For E-XPE Cup Liner and U-Motion II Acetabular Cup

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Correction of functional deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture 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.

For E-XPE Cemented 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:

For E-XPE Acetabular Components

The features of the subject devices are comparable to the predicate devices in terms of the same design, indication for use, locking mechanism and sterilization method expect material and size distribution. In material respect, the subject U-Motion II E-XPE Cup Liner is made from highly cross-linked Vitamin E UHMWPE (E-XPE) which is different from highly cross-linked UHMWPE (XPE) used for "UNITED" U-Motion II Acetabular System (K122185) but is substantially equivalent to "Corin" Trinity Acetabular System ECIMA Liners (K111481) and "Encore" X-alt™ Highly Cross Linked Acetabular Liner with Vitamin E (K130365). The subject E-XPE Cemented Cup is made from E-XPE, PMMA and Co-20Cr-15W-10Ni. These materials are identical with those used for "UNITED" Full XPE Cup (K163441) except E-XPE material. The size distribution of the subject devices is within the size range of "UNITED" U-Motion II Acetabular System (K122185) and "UNITED" Full XPE Cup (K163441). The differences between subject and predicate devices would not pose issues about safety and effectiveness. Non-clinical tests were also performed and the tests results demonstrate that the subject devices are substantially equivalent to the predicate devices.

For U-Motion II Acetabular Cup

The features of the subject devices are comparable to the predicate devices (K050262, K122185) in terms of the indication for use, materials, and sterilization method except the locking design and size distribution. The differences between the subject devices and predicate devices have been validated by locking strength testing to demonstrate that the subject U-Motion II Acetabular Cup does not introduce new risk of 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 Strength Test
b. Impingement Test
c. Wear Simulation Test
d. Abrasive Wear Simulation Test
e. Range of Motion Analysis
f. Material Properties of E-XPE Material
g. 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.