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

October 6, 2017

Re: K170089
Trade/Device Name: U-motion II Acetabular System- Additional Sizes
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, MEH, KWY, LWJ
Dated: September 1, 2017
Received: September 05, 2017

Dear Ms. 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 (DICE) 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 (DICE) 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)* K170089

Device Name
U-Motion II Acetabular System— Additional sizes

Indications for Use *(Describe)*
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 pervious 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 function deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques.
The device is intended for cementless use.

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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Phone Number	+886-3-5773351 ext. 2217
Fax Number	+886-3-577156
Name of Contact Person	Gimpel Chien Regulation and Document Management
Date prepared	January 05, 2017

Name of Device

Trade Name	U-Motion II Acetabular System— Additional sizes
Common Name	Total hip prostheses

Regulation Name and Number	The device classification for **U-Motion II Acetabular System— Additional sizes** is "Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis" and is contained in the Code of Federal Regulation, under 21CFR 888.3353. This falls under the Orthopedic Panel.
Device Class	Class II
Classification Panel	Orthopaedics
Product Code	LZO, KWY, LWJ, MEH
Predicate Device	1. U-Motion II Acetabular System (K122185) 2. U-Motion II PS^{+} Cup (K132455)

U-Motion II Acetabular System— Additional sizes *510(k) Summary*

Device Description:

This device is an extension in terms of additional size to the previously cleared U-Motion II Acetabular System (K122185) and U-Motion II PS+ Cup (K132455). U-Motion II acetabular component includes U-Motion II Cup and U-Motion II XPE Cup Liner. The indications, materials, design, safety and effectiveness of U-Motion II Cup and Cup Liner are identical to the cleared U-Motion II Acetabular System (K122185) and U-Motion II PS^{+} Cup (K132455) except the dimension. The subject U-Motion II Cups are available in size Ø 50 mm and Ø 46 mm O.D. and the subject U-Motion II Cup Liners are available in 32 mm and 36 mm I.D. The 32 mm and 36 mm inserts fit the acetabular shells with 46 mm O.D. and 50 mm O.D., respectively.

Indications:

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.

The device is intended for cementless use.

Comparison to Predicate Device:

U-Motion II Acetabular System— Additional sizes has the same basic design, intended use, materials and the same manufacturing method as device of the U-Motion II Acetabular System (K122185) and U-Motion II PS^{+} Cup (K132455).

Performance Data:

The mechanical properties of this device have been evaluated, and the analysis results shown that this subjected device is not the worst case within all sizes of U-Motion II Acetabular System. These adding sizes would not affect the safety and effectiveness.