October 17, 2022

Depuy Ireland UC
% Kathy Boggs
Senior Regulatory Affairs Specialist
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K212746
Trade/Device Name: ATTUNE Revision Cones
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: August 27, 2021
Received: August 30, 2021

Dear Kathy Boggs:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212746

Device Name
ATTUNE® Revision Cones

Indications for Use *(Describe)*
The ATTUNE Revision Cones are intended for use with the DePuy Revision Knee Systems in a revision total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, posttraumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

The ATTUNE Revision cone is to be fixated into either the proximal tibia or distal femur with or without bone cement. After implantation of the cone, the mating compatible tibial or femoral component is affixed into the revision cone using bone cement.

THE POROUS TITANIUM ATTUNE REVISION CONES ARE INTENDED FOR CEMENTED OR 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Phone number	574-404-8711
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Kathy Boggs
Date prepared	October 14, 2022
Name of device	
Trade or proprietary name	ATTUNE® Revision Cones
Common or usual name	Total Knee Prosthesis
Classification name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3565 21 CFR 888.3560
Product Code(s)	MBH JWH
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: Stryker Triathlon® Tritanium® Cone Augments (K143393) Secondary Predicate: DePuy Universal Gription™ TF Cones & Acetabular Augment System (K100391) Reference Devices: DePuy ATTUNE Revision Knee System (K160700) DePuy ATTUNE Porous FB Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology (K202194)
Reason for 510(k) submission	Addition of new revision cone devices to the ATTUNE Knee System.

Device description	The ATTUNE® Revision Cones provide supplemental metaphyseal fixation when necessary to make up for either the proximal tibia or distal femur bone loss. The ATTUNE Revision Cones are available in a variety of sizes of Femoral, Concentric, Tibial Bi-Lobe, and Tibial Tri-Lobe configurations. They are compatible with select, commercially available DePuy Orthopaedics tibial base plates and stemmed femoral components.
Intended use of the device	Total Knee Arthroplasty
Indications for use	The ATTUNE Revision Cones are intended for use with the DePuy Revision Knee Systems in a revision total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, posttraumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. The ATTUNE Revision cone is to be fixated into either the proximal tibia or distal femur with or without bone cement. After implantation of the cone, the mating compatible tibial or femoral component is affixed into the revision cone using bone cement. THE POROUS TITANIUM ATTUNE REVISION CONES ARE INTENDED FOR CEMENTED OR CEMENTLESS USE.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The DePuy ATTUNE Revision Cones are similar to the predicate Stryker Triathlon Tritanium Cone Augments (K143393) and secondary predicate DePuy Universal Gription TF (Titanium Foam) Cones & Acetabular Augment System (K100391) in principle of operation, intended use, classification, design, material, and fixation.

The ATTUNE Revision Cones are manufactured from Titanium alloy (Ti-6Al-4V), whereas the predicates are manufactured from Commercially Pure Titanium, a difference of which is negligible. The subject device is available in four differently shaped configurations and 4-5 sizes, as identified on labeling. The Stryker predicate is available in three shapes of five sizes each, and the Gription TF predicate in two shapes of four sizes each. The ATTUNE Revision Cones are intended for cementless or cemented use, as are both predicates.

The subject devices and the predicate Stryker Triathlon Tritanium Cone Augments (K143393) both utilize a 3D printed titanium porous structure for biological fixation, while the predicate DePuy Universal Gription TF Cones & Acetabular Augment System (K100391) uses Gription Titanium Foam (TF).

Characteristics	Subject Device: DePuy ATTUNE Revision Cones	Primary Predicate Device: Stryker Triathlon Tritanium Cone Augments K143393	Secondary Predicate Device: DePuy Universal Gription™ TF Cones & Acetabular Augment System K100391
FDA ProCode	MBH, JWH	MBH, JWH	JWH, KRO
Intended Use	Total Knee Arthroplasty	Total Knee Arthroplasty	Total Knee Arthroplasty
Material	Titanium Alloy ASTM F-3001	CP Titanium ASTM F-1580, ASTM F-67	CP Titanium ASTM F-1580
Fixation	Cementless or Cemented	Cementless or Cemented	Cementless or Cemented
Shapes	Symmetric, asymmetric, femoral	Symmetric, asymmetric, femoral	Symmetric, femoral

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The following tests were performed (per FDA's *Class II Special Controls Guidance Document: Knee Joint Patellofemerotibial and Femerotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA*) to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

Revision Cones:

- Cone tibial fatigue testing per ASTM F1800
- Cone tibial and femoral cement pulloff test
- Biocompatibility testing
- Particulate Analysis

Magnetic Resonance Imaging safety evaluation testing was performed, and the tests evaluated the worst-case components and constructs for magnetically induced force, torque, image artefact and RF heating.
The testing concluded that there are no safety issues related to magnetic field interactions under specific conditions identified in the labeling.

The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical testing was not required to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy ATTUNE Revision Cones are substantially equivalent to the predicate devices; Stryker Triathlon Tritanium Cone Augments and DePuy Universal Gription™ TF Cones & Acetabular Augment System.