March 10, 2023

DePuy Ireland UC
Kathy Boggs
Project Leader Regulatory Affairs
Loughbeg, Ringaskiddy
Co. Cork Munster,
IRELAND

Re: K230295
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: February 2, 2023
Received: February 2, 2023

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 -S

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.

Submission Number *(if known)*

K230295

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.

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510(k) Summary

Prepared on: 2023-02-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy, Co. Cork Munster, Ireland
Applicant Contact Telephone	574-404-8711
Applicant Contact	Kathy Boggs
Applicant Contact Email	kboggs2@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ATTUNE® Revision Cones
Common Name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Classification Name	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Regulation Number	888.3565; 888.3560
Product Code	MBH; JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212746	DePuy ATTUNE® Revision Cones	MBH, JWH
K143993	Stryker Triathlon® Tritanium® Cone Augments	MBH, JWH
K202194	DePuy ATTUNE® Porous FB Tibial Base, Medialized Dome Pate	MBH, JWH

Device Description Summary

21 CFR 807.92(a)(4)

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. The ATTUNE Revision Cones are manufactured from Titanium alloy (Ti-6Al-4V).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject DePuy ATTUNE Revision Cones are the same as the predicate DePuy ATTUNE Revision Cones (K212746) in principle of operation, intended use, classification, design, raw material, and fixation. The only difference between the two devices is that the subject device is output material grade 5 chemistry (ASTM F-2924), whereas the predicate device is output material grade 23 chemistry (ASTM F-3001).

The subject ATTUNE Revision Cones and predicate ATTUNE Revision Cones are both manufactured from Titanium alloy (Ti-6Al-4V). The subject device is available in four differently shaped configurations and 4-5 sizes, as identified on labeling. These are identical to the shape and size configurations for the predicate ATTUNE Revision Cones. The ATTUNE Revision Cones are intended for cementless or cemented use, as is the predicate.

The subject devices and the predicate DePuy ATTUNE Revision Cones (K212746) both utilize AFFIXIUM™ 3DP Technology printed titanium porous structure for biological fixation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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

Oxygen Content Study
EOS M290 3D Printer Recycling Study

Clinical testing was not required to demonstrate substantial equivalence.

The subject DePuy ATTUNE Revision Cones are substantially equivalent to the predicate device; DePuy ATTUNE Revision Cones.