November 25, 2020

DePuy Ireland UC
% Kathy Boggs
Senior Regulatory Affairs Specialist
DePuy Orthopaedic, Inc.
700 Orthopaedic Drive
WARSAW IN 46582

Re: K202194
Trade/Device Name: ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
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: October 19, 2020
Received: October 20, 2020

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,

for

Ting Song, Ph.D., R.A.C.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K202194

Device Name

ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology

Indications for Use *(Describe)*

The ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are intended for cementless use within the ATTUNE® Total Knee Replacement System. Porous coated implants may be used with or without cement.

Candidates for total knee replacement include patients with a severely painful and/or impaired knee function resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).

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

(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	574-371-4945
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Kathy Boggs
Date prepared	August 03, 2020
Name of device	
Trade or proprietary name	ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
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	Primary: 21 CFR 888.3565 Secondary: 21 CFR 888.3560
Product Code(s)	Primary: MBH Secondary: JWH
Legally marketed device(s) to which equivalence is claimed	Primary Predicate for ATTUNE Porous Fixed Bearing Tibial Base: DePuy ATTUNE Knee System, K101433 Primary Predicate for ATTUNE Porous Medialized Dome Patella & Medialized Anatomic Patella: DePuy ATTUNE Medialized Dome and Anatomic Patellae, K103756 Secondary Predicate for ATTUNE Porous Fixed Bearing Tibial Base: Triathlon Tritanium Tibial Baseplate, K123486 Secondary Predicate for ATTUNE Porous Medialized Dome Patella & Medialized Anatomic Patella: Triathlon Tritanium Metal-Backed Patella, K132624 Reference Devices: DePuy ATTUNE Cementless CR & PS Femoral Components, K140881

	DePuy ATTUNE Revision Knee System, K160700 DePuy ATTUNE Total Knee System, K201347
Reason for 510(k) submission	Addition of new porous fixed bearing tibial bases and patellae devices to the ATTUNE Knee System.
Device description	The ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology are compatible with the ATTUNE Knee System composed of individually packaged femoral, tibial and patellar components designed to replace the natural articular surface of the knee joint. The femoral component is a metal implant with or without porous coating. The tibial component may be comprised of a metal tibial base with or without porous coating, and a polyethylene insert and locking components, or be an all polyethylene device. The patella component may be of an all polyethylene design or a polyethylene patella with porous metal backing.
Intended use of the device	Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. this includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.
Indications for use	The ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are intended for cementless use within the ATTUNE® Total Knee Replacement System. Porous coated implants may be used with or without cement. Candidates for total knee replacement include patients with a severely painful and/or impaired knee function resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).

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

The DePuy ATTUNE Porous Fixed Bearing (FB) Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are similar to the predicate DePuy ATTUNE Total Knee System (K101433, K103756) and the predicate Stryker Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella (K123486, K132624) in principle of operation, intended use, classification, design, materials and fixation.

The ATTUNE Porous FB Tibial Base with AFFIXIUM 3DP Technology is manufactured from Titanium alloy (Ti-6Al-4V), available in sizes 1-10, and intended for cementless or cemented use within the ATTUNE Total Knee Replacement System. The bone apposing surfaces are comprised of 3D printed fixation features with a porous and solid geometry that enable biological fixation of the implant to the bone. The proximal surface is designed to work with currently available ATTUNE FB tibial inserts.

The ATTUNE Porous Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are manufactured from 3D printed Titanium alloy (Ti-6Al-4V) substrate for the bone opposing surfaces with the articulation surface being produced from AOX ultra high molecular weight polyethylene (UHMWPE). The patellae are available in sizes 32, 35, 38, and 41mm and are intended for cementless or cemented use within the ATTUNE Total Knee Replacement System. The articular surface is designed to work with currently available ATTUNE Femoral Components.

The subject devices and the predicate Stryker Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella (K123486, K132624) both utilize a 3D printed titanium porous structure for biological fixation, while the predicate DePuy ATTUNE Total Knee System (K101433, K103756) uses cement fixation.

Tibial Base Characteristics	**Subject Device: DePuy ATTUNE Porous FB Tibial Base with AFFIXIUM 3DP Technology**	**Secondary Predicate Device: Stryker Triathlon Tritanium Tibial Baseplate K123486**	**Primary Predicate Device: DePuy ATTUNE FB Tibial Base K101433**
Material	Titanium Alloy ASTM F-136 Titanium Alloy ASTM F-3001	Titanium Alloy ASTM F-136 CP Titanium ASTM F-67	Cast Co-Cr-Mo alloy ASTM F-75
Fixation	Cementless or Cemented	Cementless or Cemented	Cemented
Sizes	Sizes 1 to 10	Sizes 1 to 8	Sizes 1 to 10

Patella Characteristics	Subject Device: DePuy ATTUNE Porous Medialized Dome and Medialized Anatomic Patellae with AFFIXIUM 3DP Technology	Secondary Predicate Device: Stryker Triathlon Tritanium Metal-Backed Patella K132624	Primary Predicate Device: DePuy ATTUNE Medialized Dome and Anatomic Patellae K103756
Material	Metal Back: Ti6Al4V Alloy (ASTM F-3001) Articulation Surface: AOX UHMWPE (ASTM F-648)	Metal Back: CP Titanium powder (ASTM F-1580) Articulation Surface: UHMWPE (ASTM F-648)	AOX UHMWPE (ASTM F-648)
Fixation	Cementless or Cemented	Cementless or Cemented	Cemented
Sizes	32, 35, 38, and 41 mm	Symmetric & Asymmetric Symmetric: 31, 33, 36, 39 mm Asymmetric: S/I: 29, 32, 35, 38, 40 M/L: 33, 36, 39, 42, 44	29, 32, 35, 38, and 41 mm

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*) in support of the ATTUNE Porous FB Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM 3DP Technology to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

Tibial Base:

- Tray fatigue testing per ASTM F1800
- Peg fatigue testing
- Fixation testing
- Biocompatibility testing

Patella:

- Peg fatigue testing
- Biocompatibility testing

Coating Characterization:

- Static interfacial shear per ASTM F1044
- Static interfacial tensile per ASTM F1147
- Interfacial shear fatigue ASTM F1160
- Abrasion testing
- Corrosion analysis per ASTM G5-14

- Chemical composition analysis per ASTM E2371, ASTM E1409, ASTM E1941-10, ASTM E1447-09
- Morphological evaluation
- Biocompatibility testing

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 DePuy ATTUNE Porous FB Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are substantially equivalent to the predicate devices; DePuy ATTUNE Total Knee System, Stryker Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella.