June 18, 2024

Depuy Ireland UC
Catherine O'Regan
Regulatory Affairs Project Lead
Loughbeg, Ringaskiddy
Cork, Ireland

Re: K240678
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: April 24, 2024
Received: April 24, 2024

Dear Catherine O'Regan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lixin Liu -S

Lixin Liu, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240678

Device Name

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

Indications for Use *(Describe)*

The ATTUNE Porous Fixed Bearing Tibial Base, Medialized DomePatella 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)

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant Contact Telephone	+35321491400
Applicant Contact	Catherine O'Regan
Applicant Contact Email	coregan1@its.jnj.com
Correspondent Name	DePuy Ireland UC
Correspondent Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Correspondent Contact Telephone	+35321491400
Correspondent Contact	Catherine O'Regan
Correspondent Contact Email	coregan1@its.jnj.com
Date prepared	June 18th, 2024
Device Name	
Device Trade Name	ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
Common 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
Regulation Number	21 CFR 888.3565; 21 CFR 888.3560
Product Code(s)	Primary: MBH Secondary: JWH
Regulatory Class	Class II

Legally Marketed Primary Predicate Device	
K202194	ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
Legally Marketed Secondary Predicate Device	
K232303	ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology

Device Description Summary

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/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).

Indications for use Comparison

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

Technological Comparison

The subject device ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are the same as the predicate DePuy ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194 & K232303) 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 devices is output material grade 23 chemistry (ASTM F-3001).

The subject ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology and predicate ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194 & K232303) are both manufactured from Titanium alloy (Ti-6Al-4V). The subject device are identical to the shape and size configurations for the predicate ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology. The ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are intended for cementless or cemented use, as is the predicate.

The subject devices and the predicate ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194 & K232303) both utilize

AFFIXIUM™ 3DP Technology printed titanium porous structure for biological fixation. K232303 is added as a secondary predicate device for MR compatibility testing and labeling.
Non-Clinical and/or Clinical Tests Summary & Conclusions
The following tests were performed (per FDA's Class II Special Controls Guidance Document: Knee Joint Patell femorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA) to demonstrate substantial equivalence of safety and effectivenss with the predicate devices: Oxygen Content Study EOS M290 3D Printer Recycling Study Clinical testing was not required to demonstrate substantial equivalence. The subject ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are substantially equivalent to the predicate devices; DePuy ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194 & K232303).