May 22, 2026

DePuy Orthopaedics, Inc.
% Susan Mullane
Associate Director, Regulatory Affairs
DePuy Ireland UC
Loughbeg
Ringaskiddy, Cork P43 ED82
Ireland

Re: K252887
Trade/Device Name: DePuy ATTUNE™ Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH
Dated: April 27, 2026
Received: April 29, 2026

Dear Susan Mullane:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and pro duction (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.

510(k) Number *(if known)*
K252887

Device Name
DePuy ATTUNE™ Knee System

Indications for Use *(Describe)*
The DePuy ATTUNE Knee System is intended for use as a total knee replacement system. Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 & Correspondent Contact Telephone	+353 21 4914000
Applicant & Correspondent Contact	Susan Mullane
Applicant & Correspondent Contact Email	smullane@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive, Warsaw, IN 46582 United States
Date prepared	May 20, 2026
Name of device	
Trade or proprietary name	DePuy ATTUNE ™ Knee System
Common or usual name	Total Knee Replacement Prosthesis
Classification name	21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3560
Product Code(s)	**OIY:** Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive **JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Legally marketed device(s) to which equivalence is claimed	**Primary Predicate:** K101433 – DePuy Attune Knee System **Additional Predicate:** K111433 – DePuy Attune Knee System **Reference Device:** K233980 – DePuy Attune Total Knee System
Reason for 510(k) submission	In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, and as per the FDA Guidance Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and Food and Drug Administration Staff (2019), DePuy Ireland UC has compiled a Traditional 510(k) Premarket Notification to modify the existing raw material processing and gamma irradiation dosing method for a subset of the DePuy Knee portfolio of implants; specifically, components of the ATTUNE Knee System (K101433, K111433): the Attune Cruciate Retaining Fixed Bearing (CR FB) and Attune Posterior Stabilized Fixed Bearing (PS FB) tibial inserts. Therefore, this is a bundled submission, and updates include the addition of ram extrusion as an alternative raw material consolidation method and splitting of the sterilization dose from a single, high dose to two doses through a combination of crosslinking and terminal sterilization.
Device description	A Total Knee Prosthesis is composed of individually packaged femoral, tibial and patellar components designed to replace the natural articular surface of the knee joint. Femoral Components The ATTUNE CR and PS Femoral Components are a metal femoral knee component intended for cemented use. The Femoral Component may be used with the native patella or a resurfaced patella. The congruency is variable and optimized throughout the range of motion. Fixed Bearing (FB) Tibial Base The ATTUNE FB Tibial Base is designed to utilize a central universal locking mechanism intended for cemented use. The tibial base incorporates a stem and keel to provide additional stability and recessed cement pockets for enhanced cement fixation. The tibial base fixation surface is textured. Fixed Bearing (FB) Tibial Insert The ATTUNE CR and PS FB Tibial Insert is a polyethylene component. The FB

	Tibial Inserts are secured to the metal FB Tibial Base. Patella Components The ATTUNE Medialized Dome Patella and Medialized Anatomic Patella is a polyethylene component. The patellar components are cemented to the native patella and articulate with the trochlear groove and condyles of the Femoral Component. The subject Attune CR and PS FB tibial inserts are manufactured from GUR 1020 AOX ultra-high molecular weight polyethylene (UHMWPE) conforming to ASTM F648. The FB tibial inserts are available in ten (10) sizes, each size being available in varying thicknesses. The Attune FB tibial inserts were originally approved under K101433 and K111433.
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.
Indications for use	The DePuy Attune Knee System is intended for use as a total knee replacement system. Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.
Substantial equivalence	The introduction of ram extrusion as an alternative raw material consolidation method and the splitting of the sterilization dose into two doses (crosslinking of raw material and terminal sterilization of finished good) does not impact product intended use, performance, safety, effectiveness, biocompatibility, standards compliance, or labeling set forth by the predicate device.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE	
Below is a summary of the technological characteristics of the subject device compared to the predicate device, as support by performance testing:	

Characteristic	Subject Device: DePuy Attune™ Knee System	Primary Predicate: DePuy Attune Knee System (K101433)	Additional Predicate: DePuy Attune Knee System (K111433)	Reference device: ATTUNE™ Total Knee System (K233980)
Material	AOX UHMWPE (RAM extrusion)	AOX UHMWPE (Compression Moulded)	AOX UHMWPE (Compression Moulded)	AOX UHMWPE (Compression Moulded)
Fixation Surface	Cemented	Same	Same	Same
Sterilization Method	Gamma Irradiation	Same	Same	Same
Sterilization Dose	First dose: 50- 60kGy Second dose: 25-40kGy	75- 90kGy	75- 90kGy	75- 90kGy
Packaging	Polyurethane bag, polyethylene foam, inner/outer PETG trays sealed with Tyvek lids, carton, shrink wrapped.	Same	Same	Same
Shelf Life	8 years	5 years	5 years	8 years

PERFORMANCE DATA

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

The following tests and evaluations were performed to determine impact of the addition of ram extrusion as an alternative raw material consolidation method and splitting of the sterilization dose from a single, high dose to two doses through a combination of crosslinking and terminal sterilization:

- ISO 14243-2:2016: Wear of total knee-joint prostheses – Part 2: Methods of measurement
- ASTM F1877-05: Standard Practice for Characterization of Particles
- ASTM F2777-16: Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
- ASTM F648-21: Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
- ANSI AAMI ISO 11137-1:2006/(R)2015: Sterilization of health care products – Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
- ASTM E2023-11: Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities
- ASTM F2003-02 (Reapproved 2015): Standard Practice for Accelerated Aging of Ultra-High-Molecular-Weight Polyethylene after Gamma Irradiation in Air
- ASTM D1505-18: Standard Test Method for Density of Plastics by the Density-Gradient Technique
- ASTM F625-10 (Reapproved 2016): Standard Test Method for Measurement of Enthalpy of Fusion Percent Crystallinity and Melting Point of Ultra-High-Molecular-Weight Polyethylene by Means of Differential Scanning Calorimetry
- ASTM F2102-17: Standard Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants
- ASTM F281-19: Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy
- ASTM D638-14 Standard Test Method for Tensile Properties of Plastics

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

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

Based on the intended use, indications for use, and technological characteristics supported by performance testing, it can be concluded that the subject DePuy Attune™ Knee System are substantially equivalent to the predicate devices.