June 25, 2026

DePuy Ireland UC
% Paige Myers
Senior Regulatory Affairs Specialist
Depuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K261458
Trade/Device Name: ATTUNE Total Knee System; ATTUNE Cementless 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 Codes: JWH, MBH, OIY
Dated: May 1, 2026
Received: May 1, 2026

Dear Paige Myers:

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 production (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 Management System Regulation (QMSR) (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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.06.25 17:15:21 -04'00'

for Lixin Liu, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261458

Please provide the device trade name(s).

ATTUNE Total Knee System ;
ATTUNE Cementless Knee System

Please provide your Indications for Use below.

ATTUNE™ Total Knee System Indications for Use
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.

ATTUNE™ Cementless Knee System Indications for Use
The ATTUNE™ Cementless CR and PS Femoral Components are intended for cementless use within the ATTUNE™ 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, or a failed previous implant (provided that adequate bone is present).

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).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

DePuy Synthes

510(K) SUMMARY
(As required by 21 CFR 807.92 and 21 CFR 807.93)

Contact Information	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant Establishment Registration Number	3015516266
Applicant Contact Telephone	+1 574-367-4249
Applicant Contact Email	pmyers1@its.jnj.com
Applicant Contact	Paige Myers
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive, Warsaw, IN 46582 USA
Alt. Contact Telephone	+1 925-890-1497
Alternate Contact Email	Mliao7@its.jnj.com
Alternate Contact Name	Michael Liao
Date prepared	1 May 2026
Name of device	
Trade or proprietary name	ATTUNE™ Total 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)	**JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer **OIY**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: **K111433** - DePuy Attune ™ Knee System Secondary Predicate: **K170806** – ATTUNE Cemented Tibial Base, Fixed Bearing

	Reference Device: **K233980** – Bundled Knee MRI - ATTUNE, LPS, Sigma HP Uni
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, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include an updated surgical technique for DePuy ATTUNE™ Total Knee System (K111433, K170806). Additionally, cases and trays that are associated with this new surgical technique are being introduced as accessories to the existing implant devices.
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. The femoral component is a metal implant without a porous coating. The tibial component may be an all polyethylene component or comprised of a metal tibial base without porous coating, and a polyethylene insert and locking components. The patella component may be of an all polyethylene design.
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 disabled 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	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	There are no changes in design, manufacturing, principle of operation, indication, or intended use. The only change is the creation of an additional surgical technique for the existing implants and the addition of new case and trays that are now to be considered as device accessories.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE
PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
The following tests were performed to address: - Simulated Wear Performance - Computation Wear Analysis 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
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject device, DePuy ATTUNE Total Knee System, is substantially equivalent to the predicate ATTUNE Total Knee System (K11433, K170806).

Contact Information	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant Establishment Registration Number	3015516266
Applicant Contact Telephone	+1 574-367-4249
Applicant Contact Email	pmyers1@its.jnj.com
Applicant Contact	Paige Myers
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive, Warsaw, IN 46582 USA
Alt. Contact Telephone	+1 925-890-1497
Alternate Contact Email	Mliao7@its.jnj.com
Alternate Contact Name	Michael Liao
Date prepared	1 May 2026

Name of device	
Trade or proprietary name	ATTUNE ™ Cementless Knee System
Common or usual name	Total Knee Prosthesis
Classification name	21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Class II - 21 CFR 888.3565
Product Code(s)	**MBH**: Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer **JWH**: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: **K140881** - ATTUNE™ Knee System- Cementless CR and PS Femoral Components Secondary Predicate: **K202194** – ATTUNE™ Porous Fixed Bearing Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology Reference Devices: **K233980** – Bundled Knee MRI - ATTUNE, LPS, Sigma HP Uni, **K232303** - ATTUNE™ Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
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, Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff (June 2007), DePuy Ireland UC has compiled a Bundled Traditional 510(k) Premarket Notification to modify labeling to include an updated surgical technique for DePuy, ATTUNETM Cementless Knee System (K140881). Additionally, cases and trays that are associated with this new surgical technique are being introduced as accessories to the existing implant devices
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. The femoral component is a metal implant with or without a porous coating. The tibial component may be an all polyethylene component or comprised of a metal tibial base without porous coating, and a polyethylene insert and locking components. The patella component may be of an all polyethylene design.

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 disabled 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™ Cementless CR and PS Femoral Components are intended for cementless use within the ATTUNE™ 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, or a failed previous implant (provided that adequate bone is present). 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).
Substantial Equivalence	There are no changes in design, manufacturing, principle of operation, indication, or intended use. The only change is the creation of an additional surgical technique for the existing implants and the addition of new case and trays that are now to be considered as device accessories.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE
PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
The following tests were performed: - Computational Wear Analysis - Cemented Fixation Strength

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
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy ATTUNE Cementless Knee System is substantially equivalent to the predicate ATTUNE Knee System – Cementless (K140881) and the ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194).