August 25, 2021

DePuy Ireland UC
Brad Osborne
Regulatory Specialist III
Loughbeg
Ringaskiddy, Co Cork
Ireland

Re: K211609
Trade/Device Name: ATTUNE® Medial Stabilized (MS) Fixed Bearing (FB) Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, OIY
Dated: August 11, 2021
Received: August 12, 2021

Dear Brad Osborne:

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, Ph.D.
Assistant Director
DHT6A: Division of Spinal 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.

510(k) Number *(if known)*

K211609

Device Name
ATTUNE® Medial Stabilized Fixed Bearing (MS FB) Insert

Indications for Use *(Describe)*
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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	574-404-3872
Fax number	574-371-4987
Establishment Registration Number	3015516266
Name of contact person	Brad Osborne
Date prepared	24th May, 2021
Name of device	
Trade or proprietary name	ATTUNE® Medial Stabilized Fixed Bearing (MS FB) Insert
Common or usual name	Total Knee Arthroplasty Prosthesis
Classification name	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, polymer/Metal/Polymer Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3560, 21 CFR 888.3565, 21 CFR 888.3560
Product Code(s)	JWH MBH OIY
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: DePuy ATTUNE Knee System CR FB Insert (K101433) Secondary Predicate: Zimmer Biomet Persona MC Insert (K150090) Reference Predicate: ATTUNE All-Polyethylene Tibia (K193057) ATTUNE Revision LPS Inserts (K191779) ATTUNE Knee System CR FB Insert (K201347)
Reason for 510(k) submission	This 510(k) requests clearance of the ATTUNE Medial Stabilized Fixed Bearing (MS FB) Insert for use in the previously cleared ATTUNE Knee System.
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 with or without porous coating, and a polyethylene insert and locking components. The patella component may be of an all polyethylene design or a polyethylene patella with porous metal backing. The ATTUNE Medial Stabilized FB Insert is an asymmetrical fixed bearing tibial insert that will form part of the ATTUNE Knee system. It is designed to work with the ATTUNE CR femur and any of the ATTUNE Fixed Bearing Tibial Base options. The insert can be used with or without the posterior cruciate ligament.
Intended use of the device	Total Knee Arthroplasty
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.

Characteristics	Subject Device: DePuy Synthes ATTUNE® Knee System Medial Stabilized Fixed Bearing (MS FB) Inserts	Primary Predicate Device: DePuy Synthes ATTUNE® Knee System Cruciate Retaining (CR) Fixed Bearing Insert (K201347)	Secondary Predicate Device: Zimmer Biomet Persona Knee System Medial Congruent (MC) Insert (K150090)
Intended Use	Total knee arthroplasty	Total knee arthroplasty	Total knee arthroplasty
Indications for Use	Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, posttraumatic arthritis, rheumatoid arthritis, or a failed previous implant.	Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, posttraumatic arthritis, rheumatoid arthritis, or a failed previous implant.	This device is indicated for patients with severe knee pain and disability due to: Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis Collagen disorders, and/or avascular necrosis of the femoral condyle Post-tramatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery
Properties			
Material	AOX Antioxidant UHMWPE	AOX Antioxidant UHMWPE	Vivacit-E (R) Antioxidant UHMWPE
Design Features			
Articulating Geometry	Asymmetric	Symmetric	Asymmetric
Packaging Description			
Components	Sterile Package	Sterile Package	Sterile Package
Sterility			
Sterile Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

The subject ATTUNE Medial Stabilized Fixed Bearing (MS FB) Insert is identical to the primary predicate DePuy ATTUNE® Knee System [K101433] in intended use, material, and fixation and overall similar in design. The subject and predicate systems are intended for total knee arthroplasty; are components of modular tibia; are made of antioxidant UHMWPE; and are intended for use in cemented or uncemented constructs. Differences include a minor change to the geometry of the articulating surface.

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*) to demonstrate substantial equivalence of safety and efficacy with the predicate device: • Contact Area & Pressure • Constraint • Tibiofemoral Range of Motion 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 testing is required to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy ATTUNE Medial Stabilized Fixed Bearing (MS FB) Inserts are substantially equivalent to the predicate DePuy Synthes ATTUNE Knee System Cruciate Retaining (CR) Fixed Bearing Insert.