January 30, 2020

DePuy Ireland UC
% Kellie Myers
Senior Regulatory Affairs Specialist
DePuy Synthes, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K193057
Trade/Device Name: ATTUNE All Polyethylene Tibia
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
Dated: October 31, 2019
Received: November 1, 2019

Dear Kellie 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 (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
Acting 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: 06/30/20
See PRA Statement below.

510(k) Number *(if known)*

K193057

Device Name

ATTUNE All Polyethylene Tibia

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.

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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	574-372-7276
Fax number	574- 371-4987
Establishment Registration Number	3015516266
Name of contact person	Kellie Myers
Date prepared	27 September 2019
Name of device	
Trade or proprietary name	ATTUNE All Polyethylene Tibia
Common or usual name	Total Knee Arthoplasty Prosthesis
Classification name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3560
Product Code(s)	JWH
Legally marketed device(s) to which equivalence is claimed	***Darwin Knee System***, K943462 ***Darwin Knee System (Cruciate-Substituting) Porous Coated and Non-Porous Coated***, K950010 ***P.F.C. Cruciate Retaining Knee System (Size 1.5)***, K961685 ***P.F.C. Sigma Knee System (Size 1.5)***, K971189 ***DePuy ATTUNE Knee System***, K101433
Reason for 510(k) submission	This 510(k) submission is to add the ATTUNE All Polyethylene Tibia to the currently cleared ATTUNE Knee System.
Device description	The subject device is an all polyethylene tibia component made from AOX Polyethylene that mates with existing ATTUNE cemented (K101433) and cementless (K140881) femoral components, and existing ATTUNE patella components (K103756).
Intended use of the device	Cemented 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.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE						
Characteristics	**Subject Device: DePuy Synthes ATTUNE All Poly Tibia**	**Predicate Device #1: Darwin Knee System (K943462)**	**Predicate Device #2: Darwin Knee System (Cruciate-Substituting) Porous Coated and Non-Porous Coated (K950010)**	**Predicate Device #3: P.F.C. Cruciate Retaining Knee System (Size 1.5) (K961685)**	**Predicate Device #4: P.F.C. Sigma Knee System (Size 1.5) (K971189)**	**Predicate Device #5: ATTUNE Knee System (K101433)**
Intended Use	Total knee arthroplasty	Total knee arthroplasty	Total knee arthroplasty	Total knee arthroplasty	Total knee arthroplasty	Total knee arthroplasty
Properties						
Material	AOX UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE	AOX UHMWPE
Fixation	Cemented	Cemented	Cemented	Cemented	Cemented	Cemented
Sizes	**Cruciate-Retaining (CR)** • Sizes 1-10 with 5, 6, 7, 8, 9, 10 and 12mm options for each **Posterior-Stabilized (PS)** • Size 1-10 with 5, 6, 7, 8, 9, 10 and 12mm options for each	**Curved (CR)** • Sizes 2, 2.5, 3, 4, and 5 with 8mm, 10mm, 12.5 mm, and 15mm options for each	**Stabilized (PS)** Sizes 2, 2.5, 3, 4, and 5 with 8mm, 10mm, 12.5 mm, and 15mm options for each	**Curved (CR)** Size 1.5 with 8mm, 10mm, 12.5 mm, and 15mm options	**Stabilized (PS)** Size 1.5 with 8mm, 10mm, 12.5 mm, and 15mm options	**CR Fixed Bearing Tibial Inserts** • Sizes 1-10 with 5, 6, 7, 8, 10, 12, 14, 16mm options for each **PS Fixed Bearing Tibial Inserts** • Sizes 1-10 with 5, 6, 7, 8, 10, 12, 14, 16 mm options for each
Design Features						
Cruciate Retaining (CR) Tibia	Posterior cut-out	Posterior cut-out	N/A	Posterior cut-out	N/A	Posterior cut-out
Posterior Stabilized (PS) Tibia	Posterior spine	N/A	Posterior spine	N/A	Posterior spine	Posterior spine

Modularity	Monobloc tibial component made of all polyethylene	Monobloc tibial component made of all polyethylene	Monobloc tibial component made of all polyethylene	Monobloc tibial component made of all polyethylene	Monobloc tibial component made of all polyethylene	Tibial inserts snap into modular tibial trays
Packaging						
Sterile Method	Gamma radiation (75kGy to 90 kGy) (50-60 kGy crosslinking dose, then 25-40 kGy terminal sterilization dose)	Gamma radiation (25kGy to 50 kGy single dose)	Gamma radiation (25kGy to 50 kGy single dose)	Gamma radiation (25kGy to 50 kGy single dose)	Gamma radiation (25kGy to 50 kGy single dose)	Gamma radiation (75kGy to 90 kGy single dose)
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Shelf Life	5 years	5 years	5 years	5 years	5 years	5 years
Packaging Description	Inner foil pouch laminated out of foil/LLDPE/Polyester materials and vacuumed, packaged inside a Tyvek/blister tray with a foam protector configuration	Inner foil pouch laminated out of foil/LLDPE/Polyester materials and vacuumed, packaged inside a Tyvek/blister tray with a foam protector configuration	Inner foil pouch laminated out of foil/LLDPE/Polyester materials and vacuumed, packaged inside a Tyvek/blister tray with a foam protector configuration	Inner foil pouch laminated out of foil/LLDPE/Polyester materials and vacuumed, packaged inside a Tyvek/blister tray with a foam protector configuration	Inner foil pouch laminated out of foil/LLDPE/Polyester materials and vacuumed, packaged inside a Tyvek/blister tray with a foam protector configuration	Inner foil pouches and outer rigid blister trays with Tyvek lids
Compatible Components						
CR Tibial Component	ATTUNE CR Femoral Components (porous coating (PC) or no PC)	P.F.C. II CR Femoral Component (PC or no PC)	P.F.C. II CS Femoral Component (PC or no PC)	P.F.C. II CR Femoral Component (PC or no PC)	P.F.C. II CS Femoral Component (PC or no PC)	ATTUNE CR Femoral Component (PC or no PC) ATTUNE Fixed Bearing Tibial Baseplates

	ATTUNE Medialized Dome Patella; ATTUNE Medialized Anatomic Patella	P.F.C. II System Oval-Dome Patella	P.F.C. II System Oval-Dome Patella	P.F.C. II System Oval-Dome Patella	P.F.C. II System Oval-Dome Patella	ATTUNE Medialized Dome Patella; ATTUNE Medialized Anatomic Patella
PS Tibial Component	ATTUNE PS Femoral Components (PC or no PC)	P.F.C. II CR Femoral Component (PC or no PC)	P.F.C. II CS Femoral Component (PC or no PC)	P.F.C. II CR Femoral Component (PC or no PC)	P.F.C. II CS Femoral Component (PC or no PC)	ATTUNE PS Femoral Components (PC or no PC) ATTUNE Fixed Bearing Tibial Baseplates
	ATTUNE Medialized Dome Patella; ATTUNE Medialized Anatomic Patella	P.F.C. II System Oval-Dome Patella	P.F.C. II System Oval-Dome Patella	P.F.C. II System Oval-Dome Patella	P.F.C. II System Oval-Dome Patella	ATTUNE Medialized Dome Patella; ATTUNE Medialized Anatomic Patella

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*) on the ATTUNE All Polyethylene Tibia to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- Contact Area / Pressure (PS and CR)
- Wear (PS and CR)
- Constraint on tibiofemoral interface (PS and CR)
- Spine Fatigue (PS)
- C2 Fixation Testing (PS)
- Range of Motion (PS and CR)
- The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI AAMI ST-72:2011.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical testing was conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy Synthes ATTUNE All Polyethylene Tibia is substantially equivalent to the predicate Sigma All Polyethylene Tibia cleared under Darwin Knee System (K943462), Darwin Knee System (Cruciate-Substituting) Porous Coated and Non-Porous Coated (K950010), P.F.C. Cruciate Retaining Knee System (Size 1.5) (K961685), P.F.C. Sigma Knee System (Size 1.5) (K971189), and DePuy ATTUNE Knee System (K101433).