June 18, 2020

Mary Wood
Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K201347
Trade/Device Name: DePuy ATTUNE™ Total 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, MBH
Dated: May 13, 2020
Received: May 21, 2020

Dear Mary Wood:

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 -S

Ting Song, Ph.D., R.A.C.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201347

Device Name
ATTUNE Total Knee System

Indications for Use *(Describe)*
The DePuy Attune Total Knee System is intended for cemented or noncemented 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.

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5. 510k Summary

510(K) SUMMARY

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Drive Warsaw, Indiana 46582
Phone number	812-219-1298
Fax number	N/A
Establishment Registration #	1818910
Name of contact person	Mary Wood
Date prepared	May 8, 2020
Name of device	
Trade or proprietary name	ATTUNE™ Total Knee System
Common or usual name	Total Knee Arthroplasty Prosthesis
Classification name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3560 21 CFR 888.3565
Product Code(s)	OIY, JWH, MBH
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: DePuy ATTUNE Knee System, K101433 Reference Predicates: DePuy ATTUNE PS Knee System, K111433 DePuy ATTUNE Medialized Dome and Anatomic Patellae Components, K103756 ATTUNE Total Knee System – Cementless CR & PS Femoral Components, K140881
Reason for 510(k) submission	The purpose of this submission is to extend the current approved shelf life of 5 years to 8 years.
Device description	The subject device is a polyethylene tibial inserts and patella component made from AOX Polyethylene that mates with existing cemented and noncemented femoral and tibial base components

Intended use of the device	The DePuy Attune Total Knee System is intended for cemented and noncemented use as a total knee replacement 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.

Summary of Technologies/ Substantial Equivalence Discussion	
The purpose of this submission is to propose a change in shelf life from 5 years to 8 years for the ATTUNE AOX Fixed Bearing Tibial Inserts for both CR (Cruciate Retaining) and PS (Posterior Stabilized) as well as the Medialized Dome and Anatomic Patellae components There are no other modifications associated with the currently marketed products. The intended use, product design, principle of operation and materials are not impacted by this change. The testing provided below was used to support equivalence to the predicate devices.	
Non-Clinical Testing:	The following testing was conducted (in compliance with FDA Guidance, *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA*) to demonstrate substantial equivalence of safety and efficacy with the predicate devices: • Material Oxidation Index/Resistance Testing (ASTM F2102-17, ASTM F2003) • Wear Testing with Particle Analysis (ISO 14243-2, ISO 14243-3, ASTM F1877-05)
Clinical Testing:	Clinical testing was not necessary to determine substantial equivalence between the ATTUNE Polyethylene Fixed Bearing Tibia Inserts and Patella components and the predicate devices.
Conclusions drawn from non-clinical and clinical data	The subject ATTUNE Polyethylene Fixed Bearing Tibia Inserts and Patella components with 8 year shelf life are substantially equivalent to the predicate ATTUNE Polyethylene Fixed Bearing Tibia Inserts and Patella components with 5 year shelf life.

Note: There have been no modifications made to the **intended use, design, biocompatibility, materials, sterilization or packaging** of the existing **DePuy ATTUNE Knee System**.

The only modification being sought via this Special 510(k) submission is a change in the shelf life of the ATTUNE C/R Fixed Bearing Insert, ATTUNE P/S Fixed Bearing Insert and the ATTUNE Medialized Dome and Anatomic Patellae components which are made from AOX Polyethylene that is gamma irradiated.

The ATTUNE Knee System is not an invitro-diagnostic device.

Submission Purpose

The purpose of this submission is to propose a change in shelf life from 5 years to 8 years for the ATTUNE AOX Fixed Bearing Tibial Inserts for both CR (Cruciate Retaining) and PS (Posterior Stabilized) as well as the Medialized Dome and Anatomic Patellae components. A complete list of the affected devices is provided as **Exhibit A**. The change will require an update to the shelf life indicated on the Labeling. Draft labeling is provided as **Exhibit B**.

There are no other modifications associated with the currently marketed product predicate ATTUNE Total Knee System. The intended use, product design, principle of operation and materials are not impacted by this change.

Device Description

The ATTUNE CR Fixed Bearing Tibial inserts are available in sizes 1-10 and in thicknesses of 5, 6, 7, 8, 10, 12, 14, 16, and 18mm. They are manufactured from AOX ultra high molecular weight polyethylene.

The ATTUNE PS Fixed Bearing Tibial Inserts are available in sizes 1-10 and in thicknesses of 5, 6, 7, 8, 10, 12, 14, 16, 18, 20, and 22mm. They are manufactured from AOX ultra high molecular weight polyethylene.

The ATTUNE Medialized Dome and Medialized Anatomic Patellae are available in sizes 29, 32, 35, 38, and 41mm. They are manufactured from AOX ultra high molecular weight polyethylene.

The proposed change to the shelf life of the subject AOX components will have no impact to the predicate, ATTUNE Knee System (K101433, K111433, K103756, K140881) which are intended for both cemented and noncemented use.

Materials

The subject ATTUNE Fixed Bearing Tibial Inserts and Patellae components are manufactured from AOX Polyethylene. This change proposes a shelf life change from 5 to 8 years; no material or sterilization changes are proposed.

Design

No design changes are proposed for this submission. The change is to extend the shelf life of the existing ATTUNE AOX Fixed Bearing Tibial Inserts and Patellae components from 5 years to 8 years.