April 16, 2020

DePuy Ireland UC
% Brad Osborne
Regulatory Affairs Specialist II
DePuy Synthes, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K193549
Trade/Device Name: SIGMA High Performance (HP) Partial Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: HRY, OIY
Dated: February 17, 2020
Received: February 18, 2020

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,

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K193549

Device Name
SIGMA High Performance (HP) Partial Knee System

Indications for Use *(Describe)*

INDICATIONS

The SIGMA High Performance Partial Knee System is indicated for single compartmental knee replacement in skeletally mature individuals with osteoarthritis, post-traumatic arthritis of the tibiofemoral articular surfaces or a history of gout or pseudogout. All components are intended for CEMENTED USE ONLY.

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	574-371-4724
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Brad Osborne
Date prepared	4/16/2020
Name of device	
Trade or proprietary name	SIGMA High Performance (HP) Partial Knee System
Common or usual name	Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer
Classification name	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	Primary: 21 CFR 888.3530 Secondary: 21 CFR 888.3560
Product Code(s)	Primary: HRY Secondary: OIY
Legally marketed device(s) to which equivalence is claimed	K070849 DEPUY GCK (SIGMA HP Partial) FEMORAL AND TIBIAL COMPONENTS K070267 DEPUY GCK (SIGMA HP Partial) TIBIAL COMPONENTS K061648 DEPUY GRADUATED COMPARTMENTAL KNEE (GCK) (SIGMA HP Partial) K101433 DEPUY ATTUNE KNEE SYSTEM

Reason for 510(k) submission	This submission describes additional inserts compatible with the previously cleared SIGMA High Performance (HP) Partial Knee System (previously referred to as DePuy Graduated Compartmental Knee or GCK) and includes a labeling update to the existing IFU.
Device description	The DePuy SIGMA® High Performance Partial Knee System is a single compartmental knee prosthesis, composed of individually packaged femoral and tibial components designed to be used in various combinations to replace the natural articular surfaces of the knee joint. The unicompartmental femoral components are Co-Cr-Mo metal implants, available with or without a porous coating. The metal backed tibial components are Co-Cr-Mo and polyethylene and are available without a porous coating. The all-polyethylene unicompartmental tibial component manufactured from polyethylene. The unicompartmental femoral components are designed for individuals who require a higher than normal degree of flexion (up to 155º).
Intended use of the device	The DePuy SIGMA HP Partial Knee System 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	**INDICATIONS** The SIGMA High Performance Partial Knee System is indicated for single compartmental knee replacement in skeletally mature individuals with osteoarthritis, post-traumatic arthritis of the tibiofemoral surfaces or a history of gout or pseudogout. All components are intended for CEMENTED USE ONLY.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	**Subject Device:** **SIGMA HP Uni AOX Insert**	**Predicate Device:** **SIGMA HP Partial Knee XLK Insert (K061648, K070267, K070849)**	**AOX Reference Device:** **DePuy ATTUNE Knee System AOX Insert (K101433)**
Intended Use	Unicondylar Knee Arthroplasty	Unicondylar or Partial Knee Arthroplasty	Total Knee Arthroplasty
Properties			
Material	AOX UHMWPE	XLK UHMWPE	AOX UHMWPE
Fixation	Cemented	Cemented	Cemented
Sizes	Tibial Inserts: 6 Sizes, 7mm-11mm thickness in 1mm increments	Femoral & Tibial Components: 6 Sizes Tibial Inserts: 6 Sizes, 7mm-11mm thickness in 1mm increments	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
Modularity	Metal femoral component and either an all polyethylene tibial component or metal tibial component with polyethylene insert	Metal femoral component and either an all polyethylene tibial component or metal tibial component with polyethylene insert	N/A
Packaging Description			
Component	Inner foil pouch laminated out of foil/LLDPE/Polyester materials and vacuumed, packaged inside a Tyvek/blister tray with a foam protector	Double PETG Blister/Tyvek	Inner foil pouches and outer rigid blister trays with Tyvek lids

Sterility			
Sterile Method	Gamma Irradiation	Gas Plasma Sterilization	Gamma Irradiation
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}
Shelf Life	5 Years	5 Years	5 Years
Purpose of Submission			
This submission adds an AOX material option to the existing legally marketed SIGMA High Performance (HP) Partial Knee System (K070267, K070849, K061648**)**. The SIGMA HP Partial AOX insert is equivalent to the primary predicate SIGMA HP Partial XLK Insert (K070267) in intended use, geometry, design, fixation, and compatibility. The AOX material is similar to the AOX UHMWPE material used in the manufacture of the legally marketed ATTUNE® Primary Knee System. All three poly materials conform to ASTM-F648. This submission also includes a labeling update to the existing SIGMA HP Partial Knee System IFU.			

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 SIGMA High Performance (HP) Partial Knee AOX Insert to demonstrate substantial equivalence of safety and efficacy with the predicate device: • Biocompatibility • UHMWPE Material Property Characterization • Range of Motion/Constraint • Contact Area/Stress • Wear Testing • Pull-Off 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
Clinical testing was not necessary to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject DePuy SIGMA High Performance Partial Knee System AOX inserts are substantially equivalent to the predicate SIGMA High Performance Partial Knee System.