November 8, 2019

DePuy Orthopaedics, Inc.
Mr. Brian Kincaid
Associate Director, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K182301
Trade/Device Name: PFC SIGMA 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: JWH, MBH
Dated: November 1, 2019
Received: November 4, 2019

Dear Mr. Kincaid:

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, PhD
Assistant Director (Acting)
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)*
K182301

Device Name
PFC SIGMA Knee System

Indications for Use *(Describe)*
Candidates for total or unicompartmental 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. In candidates for unicompartmental knee arthroplasty, only one side of the joint (the medial or lateral compartment) is affected.

The Sigma® C/R Porocoat® Femoral Components are intended for cemented or cementless use as the femoral component of a Total Knee Replacement system.

In the US, all other porous coated components have been cleared for CEMENTED USE ONLY. Any Non-Porous coated 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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"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."

Section 5: 510 (k) Summary

(As required by 21 CFR 807.92)

Submitter Information		
Name	DePuy Orthopaedics	
Address	700 Orthopedic Drive Warsaw, IN 46582	
Phone number	574-372-7337	
Fax number	574- 371-4987	
Establishment Registration Number	1818910	
Name of contact person	Brian Kincaid	
Date prepared	May 23, 2019	
Name of device		
Trade or proprietary name	PFC SIGMA Knee System	
Common or usual name	Total Knee Replacement Prothesis	
Classification name	Knee joint patellofemorotibial polymer/metal/polymer semi-contrained 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)	JWH, MBH	
Legally marketed device(s) to which equivalence is claimed. **Note: The primary predicate device is K032115. All others are additional predicate devices.**	K882234, K884796, K952830, K961685, K971189	PFC SIGMA Knee System, Tibial Tray
	K952830	PFC SIGMA Knee System, Fluted Tibial Rod
	K882234	PFC SIGMA Knee System, Taper Femoral Stem
	K063633	PFC SIGMA Knee System, Universal Stem
	K943462, K961685, K062654	PFC SIGMA Cruciate Knee System
	K950010, K952830, K971189	PFC SIGMA Knee System
	K952830, K060515	PFC SIGMA Knee System, adaptors and bolts
	K991106	PFC SIGMA Porous Modular Keel Tray
	K984158	PFC SIGMA Plus Offset Tibial Tray
	K032115 (Primary)	PFC SIGMA Co-Cr Tibial Tray

Reason for 510(k) submission	The subject of this submission is to provide magnetic resonance imaging (MRI) compatibility labeling for the PFC SIGMA Knee System. There are no proposed changes to the indications for use, the design of the product, the materials that comprise the product, or the use of the product.
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 tray with or without porous coating, and a polyethylene insert and locking components. Some metal components have modular stems, sleeves and/or modular wedges. The patella component may be of an all polyethylene design or may be a metal backed polyethylene component.
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 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 or unicompartmental 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. In candidates for unicompartmental knee arthroplasty, only one side of the joint (the medial or lateral compartment) is affected. The SIGMA® C/R Porocoat® Femoral Components are intended for cemented or cementless use as the femoral component of a Total Knee Replacement system. In the US, all other porous coated components have been cleared for CEMENTED USE ONLY. Any Non-Porous coated components are intended for CEMENTED USE ONLY.
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE	
The purpose of this submission is to change the device labeling to include information for safety and compatibility of the subject devices in the MR environment. The design features and materials of the subject devices are identical to those of the predicate devices. The indications for use are identical to the predicate devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this submission.	

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The purpose of the submission is to add MR compatibility to the device labeling for the PFC SIGMA Knee System. There are no changes to the intended use, design, materials, sterilization, packaging, shelf life, or manufacturing methods for the PFC SIGMA Knee System.

The MR environment could potentially interact with the subject devices that may impact patient safety and imaging, including movement or dislodgement of the device due to magnetically induced displacement force and/or torque, radiofrequency (RF) induced heating, and image artifacts. Methods used to evaluate MR compatibility included the Food and Drug Administration (FDA) guidance document entitled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", as well as the following standards from the American Society for testing and Materials (ASTM):

- Magnetically induced displacement force (ASTM F2052-14*)
- Torque (ASTM F2213-06)
- Radio frequency (RF) heating (ASTM F2182-11a)
- Image Artifacts (ASTM F2219-07)
- Standard Practice for marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (F2503-13)

The tests determined the effects of the MRI on the implants, and the effects of the implants on the image quality. The tests evaluated the worst-case components and constructs for RF Heating, field interactions, and image artifacts. The testing concluded that there are no safety issues related to magnetic field interactions under specific conditions identified in the labeling.

As a result, the testing supports a MR conditional label as described within the FDA's Guidance Document and the ASTM standard, F2503-13.

*Note: External test reports have been written in compliance to ASTM F2052-14. However, a single change has been made to ASTM F2052-15 to voluntarily include the determination of the maximum allowable spatial gradient of the magnetic field. This has been incorporated in the respective reports. Henceforth, all references to the standard will be ASTM F2052-14.

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 devices are substantially equivalent to the predicate devices.