DePuy Orthopaedics, Inc.
Margaret Shaughnessy
Regulatory Affairs Project Leader
DePuy (Ireland)
Loughbeg, Ringaskiddy
Cork, Co.Cork Munster P43ED82
IE

February 4, 2020

Re: K193398
Trade/Device Name: Summit DuoFix™ HA Coating
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LPH
Dated: January 7, 2020
Received: January 8, 2020

Dear Margaret Shaughnessy:

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 Vesa Vuniqi, MS
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)*
K193398

Device Name
Summit DuoFix™ HA Coating

Indications for Use *(Describe)*

Total hip replacement is indicated in the following conditions:
1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Hemi hip replacement is indicated in the following conditions:
1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty

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.

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510(K) SUMMARY

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

Submitter Information	
Name	DePuy Orthopaedics
Address	700 Orthopedic Drive Warsaw, IN 46582
Phone number	574 372 7020
Fax number	574- 371-4987
Establishment Registration Number	1818910
Name of contact person	Margaret Shaughnessy
Date prepared	28th January 2020
Name of device	
Trade or proprietary name	Summit DuoFix™ HA Coating
Common or usual name	Hip Joint Replacement Prosthesis
Classification name	Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
Class	II
Classification panel	87 Orthopedic and Rehabilitation Devices
Regulation	888.3358
Product Code(s)	MEH, LPH
Legally marketed device(s) to which equivalence is claimed	DePuy Porocoat Hip Prosthesis – K170339, K011489, K001911
Reason for 510(k) submission	The purpose of this submission is to support the manufacturing of the subject Summit DuoFix™ HA Coating components at an additional manufacturing facility for all process steps currently performed at DePuy Ireland. This includes the HA coating process step within the DePuy Ireland manufacturing site. There is also the addition of two alternative sterilization sites being added for Business Continuity Purposes. Finally, there is a modification to the packaging; converting from an outer thermoformed blister package and film pouch inner to a polyurethane sleeve protector which is vacuumed sealed in a nylon pouch which is placed inside an outer PETG blister sealed with a Tyvek lid. There are no other modifications to the product associated with these changes in comparison with the currently marketed Summit Hip System – the

	predicate and proposed device share the same intended use, product design, principle of operation, and materials.
Device description	The Summit DuoFix Hip is identical to the previously cleared Titanium Porocoat Hip stem (K170339, K011489, K001911) except for the presence of a thin layer of hydroxyapatite coating applied to the porous coated surface. The Summit DuoFix Hip is a non-modular, collarless, Titanium, tapered, press-fit femoral stem. The hip stem is manufactured from ASTM F-620-87 forged Titanium (Ti-6Al-4V) and has a sintered commercially pure Titanium bead porous coating (Porocoat®) applied to the stem. The porous coating is applied over the circumferential ridges on the proximal region of the stem. A thin coating of hydroxyapatite (HA) is sprayed over the porous coating in a uniform thickness via a plasma spray process. The HA powder used in the plasma spray process conforms to ASTM F1185-88 and ISO 13779-6 Hydroxyapatite ($Ca_5(PO_4)_3OH$) ceramic. The plasma spray process to apply the HA coating to the Summit DuoFix Stem is the same process used to coat the Pinnacle Duofix Acetabular Cup which was cleared in K192919. The HA material used for the Summit DuoFix Stem is the same as the HA material used on the Pinnacle Duofix Acetabular Cup. The distal portion of the stem has a grit blast surface finish. The hip stem consists of 10 body sizes ranging in diameter from 7 mm to 18 mm with each body size having two offset options. The design is a medially rounded trapezoid with a longitudinal ridge to optimize distal rotational stability. The Summit DuoFix hip stem uses a 12/14 taper for attachment of femoral ball heads. Femoral ball heads are intended to be used with the Summit DuoFix Hip prosthesis to provide the femoral prosthetic articular surface for the total hip arthroplasty. The femoral head articulates with an acetabular cup prosthesis that functions to restore mobility of the hip.
Intended use of the device	Total and hemi-hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in

	patients where there is evidence of sufficient sound bone to seat and support the components. Total or hemi-hip arthroplasty may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total or hemi-hip replacement outweighs the risks associated with the age of the patient and if limited demands regarding activity and hip joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in hip mobility may lead to an expectation of significant improvement in the quality of their lives.
Indications for use	Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. Hemi hip replacement is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly.

	6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

Characteristics	**Subject Device:** Summit Hip System	**Predicate Device:** Summit Duofix™ HA Hip Stem Prosthesis – K170339	**Predicate Device:** Summit Hip HA Stem – K011489	**Predicate Device:** Summit Hip HA Stem – K001991
Intended Use	Intended for Total and Hemi-Hip Arthroplasty	Intended for Total and Hemi-Hip Arthroplasty	Intended for Total Hip Arthroplasty	Intended for Total Hip Arthroplasty
Material	**Femoral Stem**: ASTM F-620-7 Forged Titanium (Ti-6Al-4V) **Porous Coating**: Commercially pure unalloyed (ASTM F67) Titanium sintered bead porous coating **HA Coating**: the HA powder used in the plasma spray process conforms to ASTM F1185-88 and ISO 13779-6 Hydroxyapatite ($Ca_5(PO_4)_3OH$) ceramic.	Same	Same	Same
Fixation	Cementless	Same	Same	Same
Stem Size	Standard Offset Sizes 1 – 10 High Offset Sizes 1 – 10	Same	Same	Same
Sterile Method	Sterilization method and dose: Cobalt-60 Gamma irradiation 25-50kGy	Same	Same	Same
Packaging	The devices are placed in a polyurethane sleeve protector which is vacuumed sealed in a nylon pouch which is placed inside an outer PETG blister sealed with a Tyvek lid	Same	Same	In the existing configuration, the device is placed into an outer thermoformed blister package and film pouch inner.

Characteristics	Subject Device: Summit Hip System	Predicate Device: Summit Duofix™ HA Hip Stem Prosthesis – K170339	Predicate Device: Summit Hip HA Stem – K011489	Predicate Device: Summit Hip HA Stem – K001991
Shelf Life	10 Year	Same	Same	Same

PERFORMANCE DATA

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

The following tests were performed on the Summit Hip to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

- Biological safety per ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".
- Sterilization validation per AAMI ANSI ISO 11137-1: 2006/(R)2010 and AAMI ANSI ISO 11137-2: 2013
- Characterization testing of Hydroxyapatite Coating as recommended per FDA Guidance: "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implant"
- Stem Fatigue Testing as per ISO 7206-4: 2010 Implants for surgery – Partial and total hip protheses- Part 4 Determination of endurance properties and performance of stemmed femoral components

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were necessary to clear the current device and thus no clinical testing was conducted here to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy Summit Hip products are substantially equivalent to the predicate Summit Hip products (K170339, K011489 and K001991)