April 26, 2018

Depuy Orthopaedics, Inc.
Daniel J. Williman
Project Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K170339
Trade/Device Name: Summit Hip System
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: LZO, JDI, LWJ, LPH, MEH, KWY, KWL, LZY
Dated: March 28, 2018
Received: March 29, 2018

Dear Daniel J. Williman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K170339

Device Name
Summit Hip System

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.

The SUMMIT POROCOAT Porous, SUMMIT DuoFix Porous, and SUMMIT Basic Press Fit stems are indicated for uncemented use only.

The SUMMIT Cemented and SUMMIT Basic Cemented stems are indicated 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.

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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<br>Warsaw, IN 46582 | |
| Phone number | 574-372-7745 | |
| Fax number | 574- 371-4987 | |
| Establishment Registration Number | 1818910 | |
| Name of contact person | Daniel J. Williman | |
| Date prepared | March 28, 2017 | |
| **Name of device** | | |
| **Trade or proprietary name** | Summit Hip System | |
| **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** | 21 CFR 888.3353, 888.3350, 888.3358, 888.3360, and 888.3390 | |
| **Product Codes** | LZO, JDI, LWJ, LPH, MEH, KWY, LZY, KWL | |
| **Predicate Devices** | K001991 | Titan Porocoat Hip Prosthesis |
| | K011489 | Summit Duofix Hip Prosthesis |
| | K013352 | Summit Cemented Hip Prosthesis |
| | K023453 | DePuy Cemented FX Cemented Hip Prosthesis |
| | K030122 | DePuy Summit Basic Press Fit Hip Prosthesis |
| | K150862 | DePuy Actis DuoFix Hip Prosthesis |
| | K123991 | DePuy Corail AMT Hip Prosthesis |
| **Reason for 510(k) Submission** | The purpose of this submission is to append to the existing indication for use statement to include hemi–hip replacement for the Summit Hip System. | |
| **Device description** | The Summit Hip System is series of tapered femoral hip stems which may be used in either total or hemi-hip arthroplasty procedures in conjunction with DePuy hip arthroplasty devices. The Summit Porous Hip Prosthesis is a series of collarless, titanium, tapered, press-fit femoral stems. The hip stem is manufactured from | |

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| | titanium alloy (Ti-6Al-4V) and has a sintered commercially pure titanium bead porous coating (Porocoat) applied to the stem. There are 10 body sizes ranging in diameter from 7mm (Size 1) to 18mm (Size 10) with each body size having two offset options. These stems are intended for uncemented use only.<br><br>The Summit DuoFix Porous Hip Prosthesis is a series of collarless, titanium alloy, tapered, press-fit femoral stems. The hip stem is manufactured from titanium alloy (Ti-6Al-4V) and has a sintered commercially pure titanium bead porous coating (Porocoat) applied to the stem with a thin layer of hydroxyapatite (HA) coating. There are 10 body sizes ranging in diameter from 7mm (Size 1) to 18mm (Size 10) with each body size having two offset options. These stems are intended for uncemented use only.<br><br>The Summit Cemented Hip Prosthesis is series a flanged, collared tapered Cobalt-Chromium femoral stems with a smooth finish. There are seven proportional body sizes with a standard offset, and six proportional body sizes with a high offset. Distal and proximal PMMA centralizers help assure the stem is centered in the femoral canal. These stems are intended for cemented use only.<br><br>The Summit Basic Cemented Hip Prosthesis is a series of flanged, collared, tapered Cobalt-Chromium-Molybdenum femoral stems with a smooth surface finish. There are seven total sizes with a constant offset. Only six of the seven sizes are available in the high offset option. A distal PMMA centralizer helps assure that the stem is centered in the femoral canal. These stems are intended for cemented use only.<br><br>The Summit Basic Press Fit Hip Prosthesis is a series of collared, tapered Titanium femoral stem with a grit-blasted finish. There are seven sizes with a constant offset and a distal centralizer to assure that the stem is centered in the femoral canal. These stems are intended for uncemented use only. |
| **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.<br><br>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:<br>1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip |

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| | dysplasia.<br>2. Avascular necrosis of the femoral head.<br>3. Acute traumatic fracture of the femoral head or neck.<br>4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.<br>5. Certain cases of ankylosis.<br><br>Hemi hip replacement is indicated in the following conditions:<br>1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.<br>2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.<br>3. Avascular necrosis of the femoral head.<br>4. Non-union of femoral neck fractures.<br>5. Certain high subcapital and femoral neck fractures in the elderly.<br>6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.<br>7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.<br><br>The SUMMIT POROCOAT Porous, SUMMIT DuoFix Porous, and SUMMIT Basic Press Fit stems are indicated for uncemented use only. The SUMMIT Cemented and SUMMIT Basic Cemented stems are indicated for cemented use only. |

**SUBSTANTIAL EQUIVALENCE INFORMATION**

The subject and predicate Summit stem devices are identical in design, materials, and coatings. Non-clinical testing demonstrated performance equivalence between the subject and predicate devices.

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

To support a determination of substantial equivalence, non-clinical testing/evaluations were conducted. The following studies were provided:

- Hip Head Center Analysis – Demonstrated that Summit stem hemi-arthroplasty constructs do not introduce new fatigue strength risks when compared to Summit stem total hip arthroplasty constructs.
- Corrosion Analyses - Demonstrated that Summit stem hemi-arthroplasty constructs pose no greater risk for corrosion when compared to the predicate device Summit and/or Actis stems.
- Range of Motion (ROM) Analysis – Concluded that the Summit stem hemi-arthroplasty constructs have ROM equivalent to that of the predicate device Actis stem hemi-arthroplasty constructs.
- Pyrogenicity Testing – Concluded that the subject devices meet the required endotoxin limits

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

No Clinical tests were required to support this premarket 510(k) submission.