Smith & Nephew, Inc.
Michelle Huettner
Director, Regulatory Affairs, Orthopaedic Division
1450 East Brooks Rd
Memphis, Tennessee 38116

Re: K211176
Trade/Device Name: Smith & Nephew Hip Systems
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LPH, MEH, LZO, KWY, MBL, KWZ
Dated: May 31, 2022
Received: June 1, 2022

Dear Rose Beifuss:

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

Limin Sun, Ph.D.
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:

List of Cleared Devices in K211176

List of Cleared Devices in K211176

1. Anthology Hip System – MR Conditional
2. BH Dual Mobility System – MR Conditional
3. Contour Acetabular System – MR Conditional
4. CPCS Cemented Hip System – MR Conditional
5. Echelon Hip System – MR Conditional
6. Femoral Heads – MR Conditional
7. HI Cup – MR Conditional
8. Modular Hip Stems – MR Conditional
9. POLARCUP – MR Conditional
10. POLARSTEM – MR Conditional,
11. R3 Acetabular System – MR Conditional
12. Redapt Monoblock Revision Femoral System – MR Conditional
13. Redapt Revision Acetabular System – MR Conditional
14. Reflection Acetabular System - Metal Shell – MR Conditional
15. Reflection All-Poly Cup – MR Conditional
16. Short Monoblock Femoral (SMF) Hip System – MR Conditional
17. SL-Plus and SLR-Plus Cementless Femoral Hip System – MR Conditional
18. Spectron EF Hip System – MR Conditional
19. Synergy Hip System – MR Conditional
20. Tandem Bipolar/Unipolar Hip System – MR Conditional

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
Tandem Bipolar/Unipolar Hip System

Indications for Use *(Describe)*

The components are indicated for the following:
1. Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
2. Rheumatoid arthritis;
3. Arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
4. Revision procedures where other treatment or devices have failed; and
5. Treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

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)

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510(k) Number *(if known)*

K211176

Device Name
Synergy Hip System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
Spectron EF Hip System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
SL-Plus and SLR-Plus Cementless Femoral Hip System

Indications for Use *(Describe)*
Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
Short Monoblock Femoral (SMF) Hip System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
Reflection All-Poly Cup

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
Reflection Acetabular System - Metal Shell

Indications for Use *(Describe)*
The components are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, and intra-operative instability and for whom all other options to constrained acetabular components have been considered.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
Redapt Revision Acetabular System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
Redapt Monoblock Revision Femoral System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
R3 Acetabular System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
POLARSTEM

Indications for Use *(Describe)*

1. Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
2. Fracture or avascular necrosis of the femoral head
3. Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement

The POLARSTEM with Ti/HA is intended for single use only and is to be implanted without bone cement.

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)

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510(k) Number *(if known)*

K211176

Device Name
POLARCUP

Indications for Use *(Describe)*

1. Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
2. Fracture or avascular necrosis of the femoral head
3. Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
4. All forms of osteoarthritis
5. Patients with hips at risk of dislocation
6. Femoral neck fracture or proximal fracture to hip joint

The titanium plasma and titanium/HA coated implants are intended to be implanted without bone cement. The uncoated implant is intended to be implanted with bone cement> The POLARCUP Dual Mobility System is intended for single 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)

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510(k) Number *(if known)*

K211176

Device Name
Modular Hip Stems

Indications for Use *(Describe)*
The indications for use in total hip arthoplasty include rheumatoid arthritis; osteoarthritis; post-traumatic arthritis; avascular necrosis and femoral neck fractures.

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)

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510(k) Number *(if known)*

K211176

Device Name
HI Cup

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
Femoral Heads

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Type of Use *(Select one or both, as applicable)*

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See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
Echelon Hip System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Type of Use *(Select one or both, as applicable)*

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
CPCS Cemented Hip System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Number *(if known)*

K211176

Device Name
Contour Acetabular System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
BH Dual Mobility System

Indications for Use *(Describe)*
The BIRMINGHAM HIP Dual Mobility Insert is intended for use in BIRMINGHAM HIP Resurfacing (BHR) System revision surgeries in cases where an acetabular cup is retained and the femoral component revised.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K211176

Device Name
Anthology Hip System

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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)

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510(k) Summary

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	31May2022
Contact Person:	Rose Beifuss Regulatory Affairs Specialist II T +1.385.253.2551
Name of Device:	Smith & Nephew Hip Systems: Anthology Hip System, BH Dual Mobility System, Contour Acetabular System, CPCS Cemented Hip System, Echelon Hip System, Femoral Heads, HI Cup, Modular Hip Stems, Polarcup, Polarstem, R3 Acetabular System, Redapt Monoblock Revision Femoral System, Redapt Revision Acetabular System, Reflection Acetabular System - Metal Shell, Reflection All-Poly Cup, Short Monoblock Femoral (SMF) Hip System, SL-Plus and SLR-Plus Cementless Femoral Hip System, Spectron EF Hip System, Synergy Hip System and Tandem Bipolar/Unipolar Hip System.
Common Name:	Hip Stem, Acetabular Component, , Prosthetic Hip Joint- HA Coated Porous Femoral Stem, Femoral Heads and Acetabular Liners, Total Hip Joint, Femoral

	Component, Cementless, Acetabular Liners, Femoral Hip Prosthesis, Total Hip Joint, Acetabular Component, Constrained Liner, Bipolar System
Device Classification Name and Reference:	21 CFR 888.3350- Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, CFR 888.3390- Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR 888.3353- Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR 888.3310 Prothesis, hip, constrained, cemented or uncemented metal/polymer
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JDI , LPH, MEH, LZO, KWY, MBL, KWZ
Primary Predicate Device:	Anthology Hip System

Additional Predicate Devices:	BH Dual Mobility System, Contour Acetabular System, CPCS Cemented Hip System, Echelon Hip System, Femoral Heads, HI Cup, Modular Hip Stems, Polarcup, Polarstem, R3 Acetabular System, Redapt Monoblock Revision Femoral System, Redapt Revision Acetabular System, Reflection Acetabular System - Metal Shell, Reflection All-Poly Cup, Short Monoblock Femoral (SMF) Hip System, SL-Plus and SLR-Plus Cementless Femoral Hip System, Spectron EF Hip System, Synergy Hip System and Tandem Bipolar/Unipolar Hip System.

Device Description:

The purpose of this Traditional 510(k) is to add “MR Conditional” labeling to the subject Smith & Nephew Hip Systems. The technological characteristics, function of the devices, packaging and sterilization remain unchanged.

No modifications have been made to the devices’ design, material, sterilization and the manufacturing processes of the previously cleared devices.

Indications for Use:

Total Hip Systems

Anthology, Contour Acetabular, CPCS Cemented, Echelon, Femoral Heads, HI Cup, R3 Acetabular, Redapt Monoblock Revision Femoral, Redapt Revision Acetabular, Reflection All-Poly Cup, Short Monoblock Femoral, SL-Plus and SLR-Plus Cementless Femoral, Spectron EF, Synergy, BH Dual Mobility

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Modular Hip Stems

The indications for use in total hip arthroplasty include rheumatoid arthritis; osteoarthritis; post-traumatic arthritis; avascular necrosis and femoral neck fractures.

POLARCUP

1. Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
2. Fracture or avascular necrosis of the femoral head
3. Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
4. All forms of osteoarthritis
5. Patients with hips at risk of dislocation
6. Femoral neck fracture or proximal fracture to hip joint

The titanium plasma and titanium/HA coated implants are intended to be implanted without bone cement. The uncoated implant is intended to be implanted with bone cement> ThePOLARCUP Dual Mobility System is intended for single use only.

POLARSTEM

1. Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis
2. Fracture or avascular necrosis of the femoral head
3. Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis,

hemiarthroplasty, surface replacement arthroplasty, or total hip replacement

The POLARSTEM with Ti/HA is intended for single use only and is to be implanted without bone cement.

Reflection Acetabular System - Metal Shell

The components are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, and intra-operative instability and for whom all other options to constrained acetabular components have been considered.

BH Dual Mobility System

The BIRMINGHAM HIP Dual Mobility Insert is intended for use in BIRMINGHAM HIP Resurfacing (BH) System revision surgeries in cases where an acetabular cup is retained and the femoral component revised.

Partial Hip Systems

Tandem Bipolar/Unipolar

Tandem Bipolar/Unipolar Hip System

The components are indicated for the following:

1. Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
2. Rheumatoid arthritis;
3. Arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
4. Revision procedures where other treatment or devices have failed; and
5. Treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

Technological Characteristics

The device design and material of the subject devices are the same as the predicate Smith & Nephew Hip Systems cleared under the premarket notifications listed in **Table 6.1**.

Performance Data

Below listed Magnetic Resonance Imaging (MRI) compatibility testing was conducted as per the FDA's guidance and the Standards listed below.

1. FDA Guidance Document: "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment: Guidance for Industry and Food and Drug Administration Staff", 20 May 2021.
2. Reporting of Computational Modeling Studies in Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff, September 21, 2016
3. IEC 60601-2-33 (Ed 3.2), "Medical electrical equipment –Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis" (2015).
4. ASTM F2182-19e2, "Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging" (2020).
5. ISO/TS 10974:2018(E) "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device".
6. ASTM F2052-15 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.
7. ASTM F2213-2017 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
8. ASTM F2182-19 - Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging
9. ASTM F2119-07 (2013) - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Substantial Equivalence Information

The subject Smith & Nephew Hip Systems are identical in design, technological characteristics, function of the devices, packaging and sterilization to the commercially available predicate devices listed in **Table 6.1** below. The only differences between the subject devices and the commercially available predicate devices were supporting MR safety testing/assessment and the addition of "MR Conditional" information to the labeling.

Table 6.1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Anthology Hip System	K052792	10/07/2005
Smith & Nephew, Inc.	BH Dual Mobility System	K171934	11/30/2017
Smith & Nephew, Inc.	Contour Acetabular System	K962541 K040680	09/17/1996 06/14/2004
Smith & Nephew, Inc.	CPCS Cemented Hip System	K970351 K823727	02/28/1997 03/08/1983
Smith & Nephew, Inc.	Echelon Hip System	K983834 K023302 K963486	02/24/1999 10/25/2002 11/27/1996
Smith & Nephew, Inc.	Femoral Heads	K021673 K022902 K022958 K072817 K083762 K093363 K100412 K110101 K914878 K963509 K971414	06/11/2002 10/02/2002 10/02/2002 05/15/2008 03/11/2009 01/26/2010 05/05/2010 04/11/2011 07/30/1992 01/27/1997 07/16/1997
Smith & Nephew, Inc.	HI Cup	K093991	04/15/2010

Smith & Nephew, Inc.	Modular Hip Stems	K921400 K900628	04/02/1993 05/09/1990
Smith & Nephew, Inc.	POLARCUP	K070278 K110135 K122244	04/16/2007 10/14/2011 08/23/2012
Smith & Nephew, Inc.	POLARSTEM	K130728 K143739	10/10/2013 04/20/2015
Smith & Nephew, Inc.	R3 Acetabular System	K070756 K083566 K092386 K093363 K102370 K113848 K182535	06/06/2007 03/03/2009 11/03/2009 01/26/2010 01/19/2011 04/27/2012 11/19/2018
Smith & Nephew, Inc.	Redapt Monoblock Revision Femoral System	K081124 K100481 K121627 K151902 K162303	07/31/2008 07/15/2010 10/15/2012 09/03/2015 05/01/2017
Smith & Nephew, Inc.	Redapt Revision Acetabular System	K150790 K160923 K171073 K182109	11/16/2015 11/17/2016 11/21/2017 11/16/2018
Smith & Nephew, Inc.	Reflection Acetabular System - Metal Shell	K002747 K021803 K022556 K022902 K033442 K071160 K920430 K932755 K990666 K960094	12/15/2000 12/19/2002 08/28/2002 10/02/2002 11/26/2003 10/05/2007 07/21/1992 05/06/1994 08/06/1999 03/27/1996
Smith & Nephew, Inc.	Reflection All-Poly Cup	K002747	12/15/2000
Smith & Nephew, Inc.	Short Monoblock Femoral (SMF) Hip System	K103256 K123012	01/31/2011 10/24/2012
Smith & Nephew, Inc.	SL-Plus and SLR-Plus Cementless Femoral Hip System	K072852 K093991 K120211 K122296	06/09/2008 04/15/2010 07/19/2012 08/28/2012

Smith & Nephew, Inc.	Spectron EF Hip System	K823723 K831884 K970351 K791125	03/09/1983 09/20/1983 02/28/1997 06/27/1979
Smith & Nephew, Inc.	Synergy Hip System	K002996 K963509 K970337 K990369 K991485	12/11/2000 01/27/1997 02/28/1997 03/12/1999 07/12/1999
Smith & Nephew, Inc.	Tandem Bipolar/Unipolar Hip System	K023743 K896580 K934353	01/23/2003 02/15/1990 04/25/1994

Conclusion

In summary, the only differences between the subject devices and the commercially available predicate devices were supporting MR safety testing/assessment and the addition of MR safety information to the labeling. These differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the subject devices. The subject Smith & Nephew Hip Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared and do not affect the safety and effectiveness of the subject devices when used as labeled. Due to the supporting documentation within this filing, it is conducted that the subject device(s) are substantially equivalent to the predicate device(s).