October 21, 2024

Smith & Nephew, Inc.
Laurel Arrigona
Senior Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K240783
Trade/Device Name: Anthology Hip Stems; CPCS Hip Stems; Femoral Heads; R3 Acetabular Liners; Spectron Hip Stems; Synergy Hip Stems
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, LWJ, KWY, MBL, KWZ
Dated: September 17, 2024
Received: September 19, 2024

Dear Laurel Arrigona:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Limin Sun -S

Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240783

Device Name
Anthology Hip System, CPCS Cemented Hip System, Femoral Heads, Spectron Hip System, 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.

Total hip systems may be indicated for use (i) with bone cement, (ii) without bone cement, or (iii) for use with or without bone cement. Refer to the product labeling and literature for specific applications.

Some of the diagnoses listed above may increase risk of complications and reduce the chance of a satisfactory result. Specifically, an increased risk of complications for revision surgery for any reason has been documented in the literature. Patient selection factors such as age, weight, and activity level can negatively affect implant longevity and increase the risk of revision surgery. Literature has shown a high likelihood of revision in younger, heavier, or more active patients. Specifically, the risk of complications is greater in obese and morbidly obese patients.

The Anthology Hip System, CPCS Cemented Hip System, and Synergy Hip System are for primary surgeries only.

The TANDEM Unipolar and Bipolar Hip System is indicated for use in patients not suitable for total hip arthroplasty, with a non-functional femoral head due to femoral neck fracture.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240783

Device Name
R3 Acetabular System

Indications for Use *(Describe)*

Acetabular 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 degenerative joint disease or any of its composite diagnoses of osteoarthritis, avascular necrosis, and traumatic arthritis.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, congenital dysplasia, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques, and fracture-dislocation of the hip.

The Constrained Liners are indicated 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 or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

Some of the diagnoses listed above are associated with an increased risk of complications and reduced chance of a satisfactory short- and long-term outcomes. Specifically, an increased risk of complications to revision surgeries for any reason has been documented in the literature. Patient selection factors such as age, weight, and activity level may negatively affect implant longevity and increase the risk of revision surgery. Literature has shown a higher likelihood of revision in younger, heavier and/or more active patients. Specifically, the risk of complications is higher in obese patients.

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.

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date of Submission:	October 19, 2024
Contact Person:	Laurel Arrigona Regulatory Affairs Manager Laurel.arrigona@smith-nephew.com Mobile: (682)758-2312
Name of Device:	Anthology Hip Stems CPCS Hip Stems Femoral Heads R3 Acetabular System Spectron Hip Stems Synergy Hip Stems
Common Name:	Prosthesis, hip, semi-constrained, metal/polymer, cemented Prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium phosphate Prostheses, hip, semi-constrained, metal/polymer, porous uncemented Prosthesis, hip, semi-constrained, metal/polymer, uncemented Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous,

Device Classification Name and Reference:	uncemented Prosthesis, hip, constrained, cemented or uncemented, metal/polymer Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented 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 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 Hip joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JDI, MBL, MEH, LPH, LWJ, LZO, KWZ, KWY

Predicate Devices:

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Anthology Hip Stems	K052792	10/07/2005
Smith & Nephew, Inc.	Global Taper Spectron Hip Stems	K970351	02/28/1997
Smith & Nephew, Inc.	Global Taper Tapered Hip System, GT Spectron	K963509	01/27/1997
Smith & Nephew, Inc.	R3 Multi-Hole Shells and 36mm XLPE Acetabular Liners	K092386	11/03/2009
Smith & Nephew, Inc.	R3 XLPE Liners	K113848	04/27/2012
Smith & Nephew, Inc.	Reflection 3 Acetabular System	K070756	06/06/2007
Smith & Nephew, Inc	Porous and Non-Porous Revision Hip Stems of the Revision Hip System and Heads with Global Taper	K963486	11/27/1996
Smith & Nephew, Inc.	Smith & Nephew Hip Systems	K211176	07/01/2022
Smith & Nephew, Inc.	Smith & Nephew MDF Revision Hip System	K081124	07/31/2008
Smith & Nephew, Inc.	Spectron Extra-Small Straight Femoral Prosthesis	K831884	09/20/1983
Smith & Nephew, Inc.	Spectron Long, Straight Femoral Prosthesis	K823722	03/08/1983
Smith & Nephew, Inc.	Synergy Cemented Hip Stem	K990369	03/12/1999
Smith & Nephew, Inc.	Synergy Porous Size 8 Hip Stem	K991485	07/12/1999
Smith & Nephew, Inc.	Total Hip Femoral Heads – 12/14 Taper	K021673	06/11/2002

Device Description:

The purpose of this Traditional 510(k) is the following:

1. To add the MR safety information to the product labels and update the MR information within the package insert for the Smith & Nephew Hip Systems included within the scope of this 510(k), and
2. To address several iterative legacy design changes made to the subject hip system components.

Indications for Use

Total Hip Systems

Anthology Hip System, CPCS Cemented Hip System, Femoral Heads, Spectron Hip System, Synergy Hip System

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-dislocations of the hip; and correction of deformity.

Total hip systems may be indicated for use (i) with bone cement, (ii) without bone cement, or (iii) for use with or without bone cement. Refer to the product labeling and literature for specific applications.

Some of the diagnoses listed above may increase risk of complications and reduce the chance of a satisfactory result. Specifically, an increased risk of complications for revision surgery for any reason has been documented in the literature. Patient selection factors such as age, weight, and activity level can negatively affect implant longevity and increase the risk of revision surgery. Literature has shown a high likelihood of revision in younger, heavier or more active patients. Specifically, the risk of complications is greater in obese and morbidly obese patients.

The Anthology Hip System, CPCS Cemented Hip System, and Synergy Hip System are for primary surgeries only.

The TANDEM Unipolar and Bipolar Hip System is indicated for use in patients not suitable for total hip arthroplasty, with a non-functional femoral head due to femoral neck fracture.

Acetabular Hip Systems

R3 Acetabular System

Acetabular 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 degenerative joint disease or any of its composite diagnoses of osteoarthritis, avascular necrosis, and traumatic arthritis.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, congenital dysplasia, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques, and fracture-dislocations of the hip.

The Constrained Liners are indicated 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 or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

Some of the diagnoses listed above are associated with an increased risk of complications and reduced chance of a satisfactory short- and long-term outcomes. Specifically, an increased risk of complications to revision surgeries for any reason has been documented in the literature. Patient selection factors such as age, weight, and activity level can negatively affect implant longevity and increase the risk of revision surgery. Literature has shown a high likelihood of revision in younger, heavier and/or more active patients. Specifically, the risk of complications is higher in obese patients.

Technological Characteristics
The device design and material of the subject Smith & Nephew Hip System devices are similar to the predicate Smith & Nephew Hip System devices cleared under the premarket notifications listed as predicates.

Performance Data
The Magnetic Resonance Imaging (MRI) compatibility testing was conducted as per the FDA's guidance "Testing and Labeling Medical Devices for Safety in the Magnetic (MR) Environment", May 20, 2021 and the standards listed below .

- Magnetically induced displacement force (ASTM F2052)
- Magnetically induced torque (ASTM F2213)
- Radiofrequency (RF) induced heating (ASTM F2182-19e2, IEC 60601-2-33, ISO/TS 10974:2018E)
- MR image artifact (ASTM F2119)

Additional testing was conducted to assess the modifications made to the subject Smith

& Nephew Hip Systems devices against their predicates.

Conclusion

The subject modified Smith & Nephew Hip Systems devices, comprised of Anthology Hip Stems, CPCS Hip Stems, Femoral Heads, R3 Acetabular System, Spectron Hip Stems, and Synergy Hip Stems, are substantially equivalent to their predicate devices. Additionally, MR labelling can be added to the subject devices due to the applicability of test results previously reviewed and cleared via K211176.