

Summary of Safety and Effectiveness
Hip System Instruments
Smith & Nephew, Inc.

Contact Person and Address

Date of Summary: November 19, 2012

Bradley Heil
 Regulatory Affairs Specialist
 Smith & Nephew, Inc.
 Orthopaedic Division
 7135 Goodlett Farms Parkway
 Memphis, Tennessee 38016
 T (901) 399-6339

Name of Device: Hip System Instruments

Common Name: Orthopaedic Surgical Instrumentation

Device Classification Name and Reference:

- 21 CFR 878.3300 – Surgical mesh
- 21 CFR 888.3010 – Bone fixation cerclage
- 21 CFR 888.3310 – Hip joint metal/polymer constrained cemented or uncemented prosthesis
- 21 CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis
- 21 CFR 888.3353 – Hip joint meta/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
- 21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented Prosthesis
- 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic 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

Predicate Devices:

- Spectron Long Straight Femoral Component (K823722);
 - Spectron Primary Femoral Component (K823727);
 - Spectron Proximal Femoral Component (K823723);
 - Spectron Neck Replacement Femoral Component (K823724);
 - Spectron Extra Small Femoral Component (K831884);
 - Ti-Fit Femoral Component (K873797);
 - Cementra Small Taper Femoral Component (Modular Hip System) (K912593);
 - Ti-Fit Femoral Component, Ti-13-13 (K914343);
 - Revision GT Femoral Component (porous and nonporous and Co-Cr heads)(Echelon) (K963486);
 - Tapered Hip Femoral Components (porous, & non-porous – Ti) (Synergy) (K963509);
 - Tapered Hip Femoral Components (HA – Ti); (Synergy) (K970337);
 - Spectron & Cobra GT Femoral Components (non-porous – Co-Cr) (K970351);
 - PLUS Bipolar CoCrMo (K982447);
 - Echelon Primary Hip Stems (K983834);
 - Synergy Cemented Hip Stems (K9903690);
 - Synergy Porous Size 8 Hip Stem (K9914850);
 - MODULAR-PLUS® Revision Stem (K994126);
 - SL-PLUS® + SLR-PLUS® with CoCrMo Ball Heads (K001942);
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Synergy HA Coated Porous Femoral Stems (Sizes 8-20 Standard Offset and Sizes 9-20 High Offset) (K002996);
SL-PLUS® lateralised stem (K021178);
Echelon Porous Plus HA Hip Stems (fully porous coated w/HA coating) – H02COAT (K023302);
UNI Hip Stem Fixcone (K024134);
MODULAR-PLUS® New Generation System (K030971);
PLUS Orthopedics cemented stem (IPM); (K031165);
MODULAR-PLUS®, new gen AX, BX, CX proximal modules (K032709);
Smith & Nephew Modular Hip (Emperion) (K042127);
ANTHOLOGY Hip Stems (K052792);
Platform Hip Stem (K052275);
Emperion Modular Hip Line Additions (Size 9, 21, 23 stems & sleeves, sleeves for stems in K042127) (K052426);
Patient Matched Hip Stems (PMHS) (K053246);
MIS Hip Stem with Stikite (K080625);
Echelon Titanium Hip System with Gender Claims (Gender Claims removed prior to 510(k) clearance) (K072817);
SL-PLUS Femoral Hips Stems (K072852);
SL-PLUS Standard and Lateral Hip Stems S-Version (K072852);
SL PLUS MIA Femoral Hip Stems (K082371);
SLR-PLUS Femoral Stems (K093991);
MDF Revision Hip System Line Additions - XSM Grit-Blasted Modular Sleeves (Sizes 11mm-27mm); MDF Proximal Reamer #1 SZ 11 XSM; and MDF Proximal Reamer #12 SZ 26/27 L. (K100481);
SMF Hip Stem Line Additions - Size -1 and 0 hip stems (Size -1 and 0 broaches/trials, and stem punch are described in the surgical technique) (K103256);
Unipolar Femoral Head, Co-Cr (K896580);
Zirconium Alloy Femoral Head (K914878);
Unipolar Head, Zirconium Alloy (K934353);
Global Taper Femoral Heads (Co-Cr) (K963486);
BioloX Alumina Ceramic Femoral Head (12/14 taper) (K981847);
Unipolar CoCrMo (K990309);
IP Ceramic Head Prostheses in Al₂O₃ and ZrO₂ (K990261);
BioloX Alumina Ceramic Femoral Head, (K991162);
Zirconium Alloy Femoral Head: 12/14 taper (Total Hip 12/14 Taper Femoral Heads) (K021673);
Zirconium Alloy Femoral Heads: 36mm Oxinium & Alumina Ceramic Heads & 36mm XLPE liners (K022958);
Smith & Nephew Modular Femoral Heads (Hemi-Arthroplasty Indications Only) (K061243);
Smith & Nephew Modular Femoral Heads – Taper Sleeve Design (Hemi-Arthroplasty Indications Only) (K062408);
Ceramic Ball Heads, BioloX® Forte Al₂O₃, 28, 32, 36 mm (K070928);
Oxinium DH (Diffusion Hardened) Femoral Heads (K081566);
BioloX Delta Ceramic Femoral Heads (K083762);
BioloX Delta Ceramic Femoral Heads (40 and 44mm) (K100412);
10/12 Taper Oxinium Femoral Heads (K110101);

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Spectron Protrusio Acetabular Component (K823725);
Spectron Metal Backed Acetabular Component (K823729);
Spectron All Poly Acetabular Component (K823728);
Ti-Fit Acetabular Component (K860275);
Opti-Fix Acetabular Component, cemented (K864857);
Spectron EF Acetabular Component (K874619);
Ti-Thread Acetabular Component (K834592);
Reflection Acetabular Component, cemented (Modular Acetabular Component) (K920430);
HA Ti-Fit Acetabular Component, Bio-Coat (K922621);
Reflection Acetabular Component, uncemented (K932755);
Reflection InterFit Acetabular Shell (K960094);
PLUS-FIT® Acetabular Cup grit blasted (K973077);
EPF®-PLUS Acetabular Cup (K972931);
Opera Hip System-Acetabular flanged Cups (K991538);
HA Coated Reflection Shells (Reflection Acetabular Shell) (K990666);
Reflection InterFit HA Coated Shell (K990666);
PE-PLUS® Cemented Acetabular Cup (K992153);
BICON-PLUS® Acetabular Components, (PE Insert) (K992154);
BOFOR® Revision Cup Cups + PE insert Std size 28 (K993874);
EPF®-PLUS Acetabular Cup Tri-Plama Coated (K994146);
Reflection Cross-Linked UHMWPE Acetabular Components 10 Mrad Irradiation Dosage (K002747);
LPC-PLUS® Acetabular Cup (K003274);
MPF acetabular cup, generation 1 (K011836);
MPF acetabular cup, generation 2 (K022120);
Reflection Modified Acetabular Shells with HA Coating (peripheral holes) (K022556);
Reflection 36mm XLPE Acet. Liners and 36mm CoCr Femoral Heads (submission name: Smith & Nephew Hip System) (K022902);
Reflection 36mm XLPE Acet. Liners and 36mm CoCr Femoral Heads (submission name: Smith & Nephew Hip System) (K022902);
Reflection Constrained Liner (K021803);
Reflection Constrained Liner – Sizes 22, 26, & 32 mm (K033442);
Reflection 3 Acetabular System – New Shell Design (Existing Porous Coating) with Poly Liner (K061253);
Reflection 3-Hole Shell with Asymmetric Porous Coating (K060630);
POLARCUP Dual Mobility System (K070278);
REFLECTION 3 Acetabular System Addition of Stik-tite Porous Coating and Lateralized Option (K070756);
Reflection XLPE Acetabular Liners 38-50mm (K071160);
R3 Constrained Liner Traditional 510(k) (K083566);
R3 Multi-Hole Shells and 36mm XLPE Liners (K092386);
Patient Specific Acetabular Reconstruction Prosthesis (K092098);
R3 XLPE Anteverted Liners (K102370);

Spectron Conversion Endoprosthesis (K823726);
Orthopedic Cable, titanium (K842977);
Opti-Fix Femoral Component, cemented (K860635);
Tri-Wedge (Hartford Hip); Femoral Component, cemented (K870128);
Ti-Fit Femoral Head (K873797);
Orthopedic Cable, SS (K875156);
Opti-Fix Collared Femoral Component (K874868);
HA Ti-Fit Femoral Component, Bio-Interface (K913916);
Opti-Fix Femoral Component, uncemented (K921400);
Tri-Wedge Femoral Component, uncemented (K921400);
HA Ti-Fit Femoral Component, Bio-Coat (K922621);
Reflection Acetabular Reinforcement Rings (K962541);
Smith & Nephew Orthopaedic Cabling System (K031162);
Contour HA Coated Reconstruction Ring (SPS) (K040680);
Accord Cable System – Troch Grip (SPS) (K043252);
R3 40 and 44mm XLPE Liners; 40 and 44mm CoCr and Oxinium Femoral Heads and Titanium
Taper Sleeves (K093363);

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. Hip System Instruments. The subject devices are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hip Systems and their cleared Indications for Use. Smith & Nephew Hip System Instruments can be organized into instrument families which are categorized as follows: Trials, Reamers, Handles, Impactors, Broaches, Guides, Cutter, Inserter/Extractor, Tightening, and Drills.

Intended Use/Indications for Use

Smith & Nephew Hip Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hip Systems and their cleared Indications for Use.

Smith & Nephew Inc. Uncemented Femoral Stems

The components are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew, Inc. Cemented Femoral Stems

The components are indicated for cemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of

trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Inc PLUS Femoral Stems

1. The Plus Bipolar prosthesis CoCrMo is intended for use in arthroplasty therapy as a result of femoral neck fractures and is to be used in conjunction with standard femoral replacement implant. This device is intended for Cementless use only.
2. The Modular-PLUS Revision Stem is intended for cementless use in fractures of the femur where a long section of bone is damaged and the stem must anchor into the distal half of the femur.
3. The SL-PLUS Stem Primary is intended for treating patients who are candidate for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. The SLR-PLUS STEM, a revision component, is also available to replace previously failed femoral hip arthroplasties. Both components can be used with or without cement. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
4. The UNI Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head has been subject to disease or trauma. It is also intended to treat previously failed hip arthroplasties. This device is intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
5. The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, posttraumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head. The SL-PLUS Lateratized Stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute). These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Smith & Nephew Inc. Patient Matched Femoral Stems

The Smith & Nephew Patient Matched Hip Stem is 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; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques;

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endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Smith & Nephew Inc. Femoral Heads

The components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Inc. PLUS Femoral Heads

1. The PLUS Fracture Head Prosthesis is intended for use in fractures of the femoral neck and fractures or avascular necrosis of the femoral head with all Plus hip stem prostheses, which have the appropriate 12/14 Morse Taper.
2. The INTRAPLANT Ceramic Head Prostheses is intended for use in total hip arthroplasty. The indications for use of the total hip replacement prosthesis include: degenerative joint disease including the osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedure where previous treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. The INTRAPLANT Ceramic Head Prostheses are to be used only with SL-PLUS and SLR-PLUS hip stems.

Smith & Nephew Inc. Hemi-Arthroplasty Only Femoral Heads

The Smith & Nephew Modular Femoral Heads are indicated for the following: noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis; rheumatoid arthritis; arthritis secondary to a variety of diseases; and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis; revision procedures where other treatments have failed; and treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement. The modular femoral heads are for single use only and are intended to be used as part of a hemihip replacement system when articulating against the natural acetabulum.

Smith & Nephew Inc. Acetabular Components

The components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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Smith & Nephew Inc. PLUS Acetabular Components

1. The PLUS-FIT Acetabular Cup is intended for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions. In normal cases, however, the surgeon will use an acetabular implant one size larger and in exceptional cases two sizes larger.
2. The PE-PLUS Acetabular Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs restructuring.
3. The BICON-PLUS Acetabular Components are intended for use in primary and revision total hip arthroplasty where the acetabular socket needs restructuring.
4. The BOFOR Revision Cup is intended to be used to replace the acetabulum in revision hip arthroplasty.
5. The POLARCUP® Dual Mobility System is indicated for: All forms of osteoarthritis; dislocation risks; progressive loss of function of the hip joint as a result of a degenerative posttraumatic; or inflammatory / rheumatic destruction of the joint; femoral head necrosis; proximal femoral fractures (especially femoral neck); status following earlier operations such as osteosynthesis, intertrochanteric osteotomies, arthrodesis or failed joint replacement. The POLARCUP® Dual Mobility System is intended for cemented or press-fit application with or without flanges and pegs for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

Smith & Nephew Inc. Constrained Acetabular Components

The Reflection Constrained Liner is a cemented or uncemented prosthesis intended to replace a hip joint. The Reflection Constrained Liner is 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.

Smith & Nephew Inc. Patient Specific Acetabular Components

The Patient Specific Acetabular Reconstruction Prosthesis is intended to be used in primary and revision surgeries where the acetabulum has deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed below. The device is for single use and is intended for cementless application.

The Patient Specific Acetabular Reconstruction Prosthesis is indicated as follows: rheumatoid arthritis, avascular necrosis, femoral neck fractures, fracture-dislocation of the hip, and unsuccessful cup arthroplasty, endoprosthesis, femoral osteotomy, or Girdlestone resection. Indications also include osteoarthritis, traumatic arthritis, slipped capita epiphysis, fused hip and diastrophic variant.

R3 40 and 44mm XLPE Liners; 40 and 44mm CoCr and Oxinium Femoral Heads and Titanium Taper Sleeves

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The components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Accord Cable System – Troch Grip (SPS)

Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below.

1. Primary total hip arthroplasty
2. Revision total hip arthroplasty
3. Any procedure using anterolateral or lateral approaches

Contour HA Coated Reconstruction Ring (SPS)

The components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously. The device is intended for single use.

Smith & Nephew Orthopaedic Cabling System

a) General orthopaedic repair procedures including patella fractures, general cerclage, trochanteric reattachment, femur and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nailing and screwing fixation techniques.

b) Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below.

1. Primary total hip arthroplasty.
2. Revision total hip arthroplasty.
3. Any procedure using anterolateral or lateral approaches.

Reflection Acetabular Reinforcement Rings

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The Reflection Acetabular Reinforcement Ring System is indicated as follows: rheumatoid arthritis, avascular necrosis, femoral neck fractures, osteomyelitis, fracture-dislocation of the hip, and unsuccessful cup arthroplasty, endoprosthesis, femoral osteoarthritis, traumatic arthritis, slipped capita epiphysis, fused hip, and diastrophic variant. Reflection Acetabular Reinforcement Rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously. The device is for single use.

Substantial Equivalence Information

The device specific instruments associated with the implant devices with which they are used are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Share the same raw materials;
- Are manufactured though the same processes;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith and Nephew Hip System Instruments are similar in design and function to competing total hip surgical instrumentation on the market.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 28, 2013

Smith & Nephew, Incorporated
% Mr. Bradley Heil
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K123598

Trade/Device Name: Hip System Instruments
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, KWL, JDG, KWY, KWZ, LPH, LWJ, LZO, LZY,
MBL, MEH, JDJ, JDQ
Dated: May 14, 2013
Received: May 14, 2013

Dear Mr. Heil:

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

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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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin D. Keith

For

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123598 (Page 1/17)

Device Name: Smith & Nephew Inc. Uncemented Femoral Stems

Indications for Use:

Smith & Nephew Uncemented Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Uncemented Hip Systems and their cleared Indications for Use.

Uncemented Femoral Stems are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth Frank -S

Division of Orthopedic Devices

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Indications for Use

510(k) Number (if known): K123598 (Page 2/17)

Device Name: Smith & Nephew, Inc. Cemented Femoral Stems
Indications for Use:

Smith & Nephew Cemented Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cemented Hip Systems and their cleared indications for Use.

Cemented Femoral Stems are indicated for cemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Orthopedic Devices

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Indications for Use

510(k) Number (if known): K123598 (Page 3/17)

Device Name: Smith & Nephew Inc PLUS Femoral Stems
Indications for Use:

Smith & Nephew PLUS Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PLUS Hip Systems and their cleared Indications for Use.

Smith & Nephew Inc PLUS Femoral Stems are indicated for:

- The Plus Bipolar prosthesis CoCrMo is intended for use in arthroplasty therapy as a result of femoral neck fractures and is to be used in conjunction with standard femoral replacement implant. This device is intended for Cementless use only.
- The Modular-PLUS Revision Stem is intended for cementless use in fractures of the femur where a long section of bone is damaged and the stem must anchor into the distal half of the femur.
- The SL-PLUS Stem Primary is intended for treating patients who are candidate for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. The SLR-PLUS STEM, a revision component, is also available to replace previously failed femoral hip arthroplasties. Both components can be used with or without cement. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
- The UNI Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head has been subject to disease or trauma. It is also intended to treat previously failed hip arthroplasties. This device is intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

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- The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, posttraumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head. The SL-PLUS Lateratized Stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute). These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

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Indications for Use

510(k) Number (if known): K123598 (Page 5/17)

Device Name: Smith & Nephew Inc. Patient Matched Femoral Stems
Indications for Use:

Smith & Nephew Patient Matched Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Patient Matched Hip Systems and their cleared Indications for Use.

Smith & Nephew Patient Matched Hip Stems 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; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; 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.

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Indications for Use

510(k) Number (if known): K123598 (Page 6/17)

Device Name: Smith & Nephew Inc. Femoral Heads

Indications for Use:

Smith & Nephew Femoral Head Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hip Systems and their cleared Indications for Use.

Smith & Nephew Hip Systems are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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Indications for Use

510(k) Number (if known): K123598 (Page 7/17)

Device Name: Smith & Nephew Inc. PLUS Femoral Heads
Indications for Use:

Smith & Nephew PLUS Femoral Head Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PLUS Hip Systems and their cleared Indications for Use.

Smith & Nephew PLUS Hip Systems are indicated for:

- The PLUS Fracture Head Prosthesis is intended for use in fractures of the femoral neck and fractures or avascular necrosis of the femoral head with all Plus hip stem prostheses, which have the appropriate 12/14 Morse Taper.
- The INTRAPLANT Ceramic Head Prostheses is intended for use in total hip arthroplasty. The indications for use of the total hip replacement prosthesis include: degenerative joint disease including the osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedure where previous treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. The INTRAPLANT Ceramic Head Prostheses are to be used only with SL-PLUS and SLR-PLUS hip stems.

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Indications for Use

510(k) Number (if known): K123598 (Page 8/17)

Device Name: Smith & Nephew Inc. Hemi-Arthroplasty Only Femoral Heads
Indications for Use:

Smith & Nephew Hemi-Arthroplasty Only Femoral Head Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hemi-Arthroplasty Hip Systems and their cleared Indications for Use.

Smith & Nephew Hemi-Arthroplasty Hip Systems are indicated for:

- noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis
- rheumatoid arthritis
- arthritis secondary to a variety of diseases
- anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis
- revision procedures where other treatments have failed
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement

The modular femoral heads are for single use only and are intended to be used as part of a hemihip replacement system when articulating against the natural acetabulum.

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510(k) Number (if known): K123598 (Page 9/17)

Device Name: Smith & Nephew Inc. Acetabular Components
Indications for Use:

Smith & Nephew Acetabular Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hip Systems and their cleared Indications for Use.

Smith & Nephew Hip Systems are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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Indications for Use

510(k) Number (if known): K123598 (Page 10/17)

Device Name: Smith & Nephew Inc. PLUS Acetabular Components

Indications for Use:

Smith & Nephew PLUS Acetabular Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PLUS Hip Systems and their cleared Indications for Use.

Smith & Nephew PLUS Hip Systems are indicated for:

- The PLUS-FIT Acetabular Cup is intended for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions. In normal cases, however, the surgeon will use an acetabular implant one size larger and in exceptional cases two sizes larger.
- The PE-PLUS Acetabular Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs restructuring.
- The BICON-PLUS Acetabular Components are intended for use in primary and revision total hip arthroplasty where the acetabular socket needs restructuring.
- The BOFOR Revision Cup is intended to be used to replace the acetabulum in revision hip arthroplasty.
- The POLARCUP® Dual Mobility System is indicated for: All forms of osteoarthritis; dislocation risks; progressive loss of function of the hip joint as a result of a degenerative posttraumatic; or inflammatory / rheumatic destruction of the joint; femoral head necrosis; proximal femoral fractures (especially femoral neck); status following earlier operations such as osteosynthesis, intertrochanteric osteotomies, arthrodesis or failed joint replacement. The POLARCUP® Dual Mobility System is intended for cemented or press-fit application with or without flanges and pegs for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

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510(k) Number (if known): K123598 (Page 11/17)

**Device Name: Smith & Nephew Inc. Constrained Acetabular Components
Indications for Use:**

Smith & Nephew Constrained Acetabular Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Constrained Hip Systems and their cleared Indications for Use.

Smith & Nephew Constrained Hip Systems are indicated for:
The Reflection Constrained Liner is a cemented or uncemented prosthesis intended to replace a hip joint. The Reflection Constrained Liner is 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.

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Indications for Use

510(k) Number (if known): K123598 (Page 12/17)

**Device Name: Smith & Nephew Inc. Patient Specific Acetabular Components
Indications for Use:**

Smith & Nephew Patient Specific Acetabular Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Patient Specific Hip Systems and their cleared indications for use.

Smith & Nephew Patient Specific Hip Systems are indicated for:

- The Patient Specific Acetabular Reconstruction Prosthesis is intended to be used in primary and revision surgeries where the acetabulum has deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed below. The device is for single use and is intended for cementless application.
- The Patient Specific Acetabular Reconstruction Prosthesis is indicated as follows: rheumatoid arthritis, avascular necrosis, femoral neck fractures, fracture-dislocation of the hip, and unsuccessful cup arthroplasty, endoprosthesis, femoral osteotomy, or Girdlestone resection. Indications also include osteoarthritis, traumatic arthritis, slipped capita epiphysis, fused hip and diastrophic variant.

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Indications for Use

510(k) Number (if known): K123598 (Page 13/17)

Device Name: R3 40 and 44mm XLPE Liners; 40 and 44mm CoCr and Oxinium Femoral Heads and Titanium Taper Sleeves

Indications for Use:

Smith & Nephew Hip Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hip Systems and their cleared Indications for Use.

Smith & Nephew Hip Systems are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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510(k) Number (if known): K123598 (Page 14/17)

Device Name: Accord Cable System – Troch Grip (SPS)

Indications for Use:

Smith & Nephew Accord Cable System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Accord Cable Systems and their cleared Indications for Use.

The Accord Cable System is indicated for:

- Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below:
 - Primary total hip arthroplasty
 - Revision total hip arthroplasty
 - Any procedure using anterolateral or lateral approaches

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510(k) Number (if known): K123598 (Page 15/17)

Device Name: Contour HA Coated Reconstruction Ring (SPS)

Indications for Use:

Smith & Nephew Contour HA Coated Reconstruction Ring Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Contour Systems and their cleared Indications for Use.

The Smith & Nephew Contour System is indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously. The device is intended for single use.

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510(k) Number (if known): K123598 (Page 16/17)

Device Name: Smith & Nephew Orthopaedic Cabling System

Indications for Use:

Smith & Nephew Orthopaedic Cabling System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Orthopaedic Cabling System and their cleared Indications for Use.

The Orthopaedic Cabling System is indicated for:

- General orthopaedic repair procedures including patella fractures, general cerclage, trochanteric reattachment, femur and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nailing and screwing fixation techniques.
- Trochanteric reattachment whenever the trochanter is osteomized in any of the procedures listed below:
 - Primary total hip arthroplasty.
 - Revision total hip arthroplasty.
 - Any procedure using anterolateral or lateral approaches.

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510(k) Number (if known): K123598 (Page 17/17)

Device Name: Reflection Acetabular Reinforcement Rings

Indications for Use:

Smith & Nephew Reflection Acetabular Reinforcement Ring Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Reflection Acetabular Systems and their cleared Indications for Use.

Smith & Nephew Reflection Acetabular Systems are indicated for:

- rheumatoid arthritis
- avascular necrosis
- femoral neck fractures
- osteomyelitis
- fracture-dislocation of the hip
- unsuccessful cup arthroplasty
- endoprosthesis
- femoral osteoarthritis
- traumatic arthritis
- slipped capita epiphysis
- fused hip
- diastrophic variant

Reflection Acetabular Reinforcement Rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously. The device is for single use.

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