DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 14, 2016

Smith & Nephew, Inc.
Mr. Michael Scott
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K161233
Trade/Device Name: Oxinium DH Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ polymer/metal semi-constrained porous-coated uncemented prothesis
Regulatory Class: Class II
Product Code: MBL, LPH, JDI, LZO
Dated: November 11, 2016
Received: November 14, 2016

Dear Mr. Scott:

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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161233

Device Name
OXINIUM DH 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.

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.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Smith & Nephew OXINIUM DH Femoral Heads

SUBMITTER: Smith & Nephew, Inc.
I. Orthopaedic Division
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Phone: (901) 396-1633
Fax: (901) 566-7159

Contact Person: Michael Scott
Date Prepared: November 11, 2016

II. DEVICE

Name of Device: OXINIUM DH Femoral Heads
Common Name: Femoral Head
Regulatory Class: 2

Classification Name, Regulation Number, Product Codes,
Hip joint metal/polymer/metal semi-constrained porous- coated uncemented prosthesis (21 CFR 888.3358), MBL, LPH
Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350), JDI
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (CFR 888.3353), LZO

III. PREDICATE DEVICE

K093363 (S.E. 01/26/2010) COCR and OXINIUM Femoral Heads – Primary Predicate
K081566 (S.E. 08/21/2008) OXINIUM DH Femoral Heads – Predicate 2
K021673 (S.E. 06/11/2002) TOTAL HIP Femoral Head-12/14 Taper – Predicate 3

The predicate devices have not been subject to a design related recall.

IV. Device Description

Femoral Heads

For proper anatomic and musculature fit, cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths. Heads are available in 10/12, 12/14, and 14/16 tapers. Certain modular heads and unipolar heads may require taper sleeves for attachment to the femoral stem taper. Heads are highly polished for reduced friction and wear. Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene liner, metal-backed acetabular component having an appropriately sized inside diameter.

The subjects OXINIUM DH Femoral Heads are metal alloy devices processed via a proprietary oxidation process and are designed as a component to replace a hip joint. The subject OXINIUM DH Femoral Heads are designed for use with existing 510(k) cleared products consisting of Smith & Nephew hip stems, acetabular shells and liners and will articulate against existing acetabular shell and liner constructs. The subject Femoral Heads are comprised of Oxidized Zirconium manufactured from wrought Zirconium (Zr) -2.5 Niobium (Nb).

The purpose of this 510(k) submission is to add additional OXINIUM DH femoral heads to the Smith & Nephew Total Hip System.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject OXINIUM DH Femoral Heads have identical indications for use, intended use and fundamental scientific technology as the primary predicate cleared by the FDA in K093363 (01/26/2010).

The subject OXINIUM DH Femoral Heads has identical intended use, similar design features, identical sterilization methods and identical material as the predicate 2 device K081566 (S.E. 08/21/2008).

The subject OXINIUM DH Femoral Heads has an identical intended use, fundamental scientific technology, sterilization method and similar design aspects as the predicate 3 device K021673 (S.E. 06/11/2002).

Like the femoral heads found in the listed predicates, the subject Smith & Nephew OXINIUM DH Femoral Heads are compatible with Smith & Nephew hip stems featuring a 12/14 taper and will articulate against existing acetabular shell and liner constructs. Therefore, the technological characteristics of the subject device are similar to the technological characteristics of the predicate device.

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the OXINIUM DH femoral heads was conducted in accordance with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process".

The subject OXINIUM DH femoral heads are permanent implants and will be classified as permanent, >30 day body contact according to ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process". The subject OXINIUM DH Femoral Heads are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standard:

ASTM F2384-10– "Standard Specification for Wrought Zirconium-2.5 Niobium Alloy for Surgical Implant Applications".

Mechanical testing

In accordance with the following guidance's/standards, Smith & Nephew has evaluated the subject devices to demonstrate substantial equivalence to the listed predicate devices.

Design verification testing was completed under the guidance of the following standards:

- ASTM F2009-00 (Reapproved 2011) - *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses*
- ASTM F2068-15 *Standard Specification for Femoral Prostheses - Metallic Implants*

- ISO 7206-6 (Second Edition) *Implants for surgery -- Partial and total hip joint prostheses -- Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components*

Mechanical tests completed/assessed were:

- Range of Motion
- Pull-Off Testing
- Environmental Corrosion Testing
- Fatigue Testing
- Torsional Disassembly Testing
- Wear Testing

Bacterial endotoxin testing was completed and met the acceptable endotoxin limits as stated in the FDA Guidance , "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers," and ANSI/AAMI ST72

The subject devices with pre-determined acceptance criteria met the acceptance criteria for all tests.

VIII. CONCLUSIONS

Based on the test results, risk analysis and additional verification evidence activities provided in the pre-market notification, the subject OXINIUM DH femoral heads are substantially equivalent to the legally marketed predicate devices cleared in: Primary Predicate: K093363 (01/26/2010), Predicate 2: K081566 (S.E. 08/21/2008), and Predicate 3: K021673 (S.E. 06/11/2002).