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

November 30, 2017

Re: K171934
Trade/Device Name: Birmingham Hip (BH) Dual Mobility Insert
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, KWY
Dated: October 26, 2017
Received: October 27, 2017

Dear Mike 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171934

Device Name
BH Dual Mobility Inserts

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Smith & Nephew BH Dual Mobility Inserts

I. SUBMITTER:

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Orthopaedic Division
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Cordova, Tennessee 38016

Phone: (901) 396-1633
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Contact Person: Michael Scott
Date Prepared: October 26, 2017

II. DEVICE

Name of Device: BH Dual Mobility Insert
Common Name: Acetabular Component
Regulatory Class: 2

Classification Name, Regulation Number, Product Codes,
Hip joint metal/polymer/metal semi-constrained porous- coated uncemented prosthesis (21 CFR 888.3358), LPH
Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350), JDI
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (CFR 888.3390), KWY

III. PREDICATE DEVICE

Primary Predicate - K110135 (S.E. 10/14/2011) POLARCUP Dual Mobility System
Predicate 2 - K070278 (S.E. 04/16/2007) POLARCUP Dual Mobility System

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

IV. Device Description

The BIRMINGHAM HIP Dual Mobility Insert prosthesis is a cross-linked UHMWPE (XLPE) insert intended for use in BIRMINGHAM HIP Resurfacing (BHR) System revision surgeries in cases where a BHR acetabular cup is retained and the femoral component revised. The BIRMINGHAM HIP Resurfacing (BHR) received initial PMA Approval under P040033 (05/09/2006).

The device consists of an XLPE insert component designed to articulate against the retained BHR acetabular cup. The insert is also designed to interface with Smith & Nephew femoral heads and THA femoral stems. During low level activity the articulation occurs between the femoral ball head and the insert with the insert remaining in a neutral position. During high level activities requiring a larger range of motion the femoral stem contacts the insert and articulation between the insert and shell will occur.

The inserts are supplied in 11 sizes between 38-58mm to match the core BHR acetabular cup size range.

The purpose of this 510(k) submission is to add a revision option for the BHR System in cases where an acetabular cup is retained and the femoral component revised.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject BH Dual Mobility Inserts have a similar intended use to the predicate POLARCUP Dual Mobility System implants (S.E. K110135 (S.E. 10/14/2011)). Additionally, the subject BH Dual Mobility Insert contains identical internal surface designs compared with the predicate POLARCUP XLPE Inserts as they relate to articulation against a femoral head. The subject BH Dual Mobility Insert size range is within the range of the existing POLARCUP insert sizes.

The subject BH Dual Mobility Insert is manufactured from identical XLPE material and follows an identical sterilization method as the predicate POLARCUP Dual Mobility System implants (S.E. K110135 (S.E. 10/14/2011)). Both the BH Dual Mobility Insert and the POLARCUP Dual Mobility System implants are available for use with metal, ceramic or Oxinium, 22 and 28mm femoral ball heads. Both the subject and predicate devices are manufactured, packaged and sterilized in the same locations and follow an identical manufacture process flow.

The Subject BH Dual Mobility Insert differences from the predicate POLARCUP Dual Mobility System implants consist of: The BH Dual Mobility Insert is intended for use against a fixed CoCrMo BH Acetabular cup whilst the POLARCUP Dual Mobility Insert is intended to articulate against the stainless steel POLARCUP Acetabular shell. Additionally, the BH Dual Mobility Insert is intended for use in a revision scenario for use against an in-situ BHR Acetabular Cup whereas the POLARCUP Dual Mobility Insert is intended for use in both primary and revision cases against a new POLARCUP shell.

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.

Therefore, the technological characteristics of the subject device are the similar to the technological characteristics of the predicate device POLARCUP Dual Mobility System implants (S.E. K110135 (S.E. 10/14/2011)).

VII. PERFORMANCE DATA

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

Biocompatibility

The biocompatibility evaluation for the BH Dual Mobility Insert 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 BH Dual Mobility Inserts 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 BH Dual Mobility Inserts are manufactured from identical polyethylene XLPE materials as the predicate devices, in accordance with the following ASTM standard: ISO 5834-2: 2011. Biocompatibility testing and rationales have been provided for the subject BH Dual Mobility Inserts.

Mechanical testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted on the proposed BH Dual Mobility Insert. Test results demonstrated that the proposed devices are substantially equivalent to the predicate POLARCUP Dual Mobility System.

Mechanical tests/assessments completed were:

- Dislocation Analysis
- Range of Motion
- Wear Testing

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

VIII. CONCLUSIONS

Based on the test results and additional verification evidence activities provided in the pre-market notification, the subject BH Dual Mobility Inserts are substantially equivalent to the legally marketed predicate devices: Primary predicate: K110135 (S.E. 10/14/2011) and Predicate 2: Predicate 2 - K070278 (S.E. 04/16/2007).