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

May 11, 2017

Smith & Nephew, Inc.
Thomas Fearnley
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K170648
Trade/Device Name: Anthem CR Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 2, 2017
Received: March 3, 2017

Dear Mr. Fearnley:

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.

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" (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.

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)*
K170648

Device Name
ANTHEM™ CR Total Knee System

Indications for Use *(Describe)*
1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

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, Inc. ANTHEM◇ CR Total Knee System

Submitted by:	Smith & Nephew, Inc. 1450 East Brooks Road Memphis, TN 38116
Date of Summary:	03/02/2017
Contact Person and Address:	Thomas Fearnley Regulatory Affairs Specialist T (901) 399-6139 F (901) 721-2421
Name of Device:	Smith & Nephew, Inc. ANTHEM◇ CR Total Knee System
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	21 CFR 888.3560 Knee Joint Patellofemorotibia polymer/metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopedics/87
Product Code:	JWH

Device Description

The ANTHEM◇ CR Total Knee System is a cruciate retaining implant design that includes CoCr femoral components and titanium tibia baseplate components, each available in multiple sizes; femorals: sizes 3 – 8 standard and 1 – 6 narrow with right and left options; tibia baseplates: size 1 – 8 with right and left options. The narrow femoral options have a slightly narrower ML width of the posterior condyles than the standard options of the same size. Additionally, a range of Genesis II CR Deep Flex Inserts (sizes 1-8; thicknesses 9-18mm – K041825) have been rebranded as Anthem CR HF Inserts to provide consistency within the total knee system. Both the Genesis II CR HF and Anthem CR HF branded inserts will remain on the market simultaneously with identical component designs. These inserts are single-use prescription devices made of ultra-high molecular weight polyethylene (UHWMPE, ASTM F648) and sterilized via ethylene oxide (ETO). The existing GENESIS II Patellas (sizes: 26 – 35mm; K951987) and ANTHEM Tibia Baseplates (K142807) are used in conjunction with the new femoral to complete the ANTHEM CR Total Knee System. The GENESIS II CR Deep Flexion Inserts (sizes: 1-8; thickness: 11-30mm; K041825) in conjunction with the GENESIS II Tibia baseplate (sizes: 1-8 with left and right options; K951987) can also be substituted in the ANTHEM CR Total Knee System.

The new femoral components of the ANTHEM CR Total Knee System leverage established marketed designs (LEGION Narrow – K112941; GENESIS II – K951987) with some changes to accommodate varied patient anatomy. All of the implants are either gamma or ETO sterilized single-use prescription devices intended to be used under the guidance of a physician at a healthcare facility.

Intended Use

The Smith & Nephew ANTHEM CR Total Knee System is intended for total knee arthroplasty.

Indications for Use

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the proposed femoral components and articular inserts of the ANTHEM CR Total Knee System are substantially equivalent to the legally marketed predicate devices (listed below in Table 1) with regard to intended use, indications for use, and performance characteristics. The primary technological differences that exist between the subject and predicate devices are the following:

- Narrower ML width of the femoral component
- Narrower anterior flange shape of the femoral component

Table 1: Substantially Equivalent Predicates to the ANTHEM Total Knee System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	ANTHEM PS Knee System	K142807	12/22/2014
Smith & Nephew, Inc.	Legion Narrow CR Knee System	K112941	12/20/2011
Smith & Nephew, Inc	Genesis II CR Deep Flexion Insert	K041825	03/11/2005
Smith & Nephew, Inc.	Genesis II Total Knee System	K951987	08/22/1995

Summary of Preclinical Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted on the proposed femoral and articular insert components of the ANTHEM Total Knee System. Test results demonstrated that the proposed devices are substantially equivalent to one or more of the previously cleared predicate devices listed in Table 1. The specific types of non-clinical testing conducted are listed below and conform to the requirements of FDA Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-constrained Total Knee Prostheses, dated April 1993:

- Contact area testing according to ASTM F2083
- Constraint testing according to ASTM F2083 and ASTM F1223

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.

Conclusion

Based on the similarities to the predicate components and a review of the mechanical testing performed, the subject devices are substantially equivalent to the predicate devices listed in Table 1.