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 22, 2014

Smith and Nephew, Incorporated
% Mr. Samir Ibrahim
Senior Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K142807
Trade/Device Name: ANTHEM PS 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: September 26, 2014
Received: September 29, 2014

Dear Mr. Ibrahim:

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 yours,

Lori A. Wiggins -S

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

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K142807

Device Name: **ANTHEM® PS Total Knee System**

Indications for Use:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The ANTHEM PS Total Knee System is indicated for use only with cement and is a single use device.

Prescription Use ___**X**___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K142807

510(k) Summary
Smith & Nephew, Inc. ANTHEM◇ PS Total Knee System

Submitted by: Smith & Nephew, Inc.
1450 East Brooks Road
Memphis, TN 38116

Date of Summary: September 26, 2014

Contact Person and Address: Samir Ibrahim, PhD, MBA, RAC
Senior Regulatory Affairs Specialist
T (901) 399-6139
F (901) 721-2421

Name of Device: Smith & Nephew, Inc. ANTHEM◇ PS 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 subject ANTHEM PS Total Knee System is a posterior stabilized implant design that includes cobalt chromium (ASTM F75) femoral components and titanium (ASTM F1472) tibia baseplate components that are intended to be used with existing GENESIS II components to complete the total knee construct. The femoral components are based on the LEGION Narrow PS (K112941) and GENESIS II PS (K951987) designs, and are available in two categories: ANTHEM Standard (Sizes: 3-8; left and right options) and ANTHEM Narrow (Sizes 1-6; left and right options). The ANTHEM Tibia Baseplates are leveraged from the GENESIS II Tibia Baseplate (K951987) design, with a modification to the stem, and provided in sizes 1-8 with left and right options. All of the implants are gamma 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 PS 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.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The ANTHEM PS Total Knee System is indicated for use only with cement and is a single use device.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the proposed femoral and tibial components of the ANTHEM PS 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
- Shorter, non-tapered stem of the tibial component

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

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Legion Narrow PS Knee System	K112941	12/20/2011
Smith & Nephew, Inc.	Genesis II PS 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 tibial 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

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.