DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 15, 2016

Smith & Nephew, Incorporated
Mr. Brad Sheals
Principal Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K160738
Trade/Device Name: ZUK Select Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX, OIY, KRR, NPJ
Dated: March 16, 2016
Received: March 17, 2016

Dear Mr. Sheals:

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 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

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)*
K160738

Device Name
ZUK Select Knee System

Indications for Use *(Describe)*

The ZUK Unicompartmental Knee System is indicated for patients with:

-Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
-Previous tibial condyle or plateau fractures with loss of anatomy or function.
-Varus or valgus deformities.
-Revision of previous arthroplasty procedures.
-These devices are indicated for cemented use only.
-The ZUK Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

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.

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)*
K160738

Device Name
ZUK Select Knee System

Indications for Use *(Describe)*

Indications for JOURNEY Unicompartmental Knee Replacement:
Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US for use without bone cement.

Indications for JOURNEY Patello-Femoral Replacement:

- Degenerative arthritis in the distal femur and patella;
- A history of patellar dislocation or patellar fracture; and
- Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew patello-femoral implants are intended for implantation with bone cement.

Indications for Combined Unicompartmental and Patello-Femoral Replacement:

- Post-traumatic arthritis;
- Degenerative arthritis; and
- Failed osteotomies and unicompartmental replacement

These indications will be used for the combined unicompartmental and patello-femoral implant device, whereby a single condyle and patello-femoral regions have been affected by one or more of these conditions. Combined Unicompartmental and Patello-Femoral implants are intended for implantation with 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.

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

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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 16, 2016
Contact Person and Address:	Brad Sheals Principal Regulatory Affairs Specialist T 901-399-6897 F 901-566-7911
Name of Device:	ZUK Select Knee System
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	21 CFR 888.3520- Knee joint femorotibial metal/polymer non-constrained cemented prosthesis 21 CFR 888.3540- Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSX, OIY, KRR, NPJ

Device Description

The purpose of this 510(k) is to notify the FDA of our intent to market previously cleared Smith & Nephew knee implants with previously cleared ZUK knee implants. Together with existing Smith & Nephew knee implants, these devices will be marketed under the trade name ZUK Select Knee System. The nature of this filing is to seek FDA clearance for these existing devices to be used in various combinations to create a bicompartmental knee replacement prosthesis. No new or modified knee implant components or new device specific instruments are being introduced to this filing.

Intended Use

Indications for JOURNEY Unicompartmental Knee Replacement:
Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

• Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed; and
• Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US for use without bone cement.

Indications for JOURNEY Patello-Femoral Replacement:

• Degenerative arthritis in the distal femur and patella;
• A history of patellar dislocation or patellar fracture; and
• Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew patello-femoral implants are intended for implantation with bone cement.

Indications for Combined Unicompartmental and Patello-Femoral Replacement:

• Post-traumatic arthritis;
• Degenerative arthritis; and
• Failed osteotomies and unicompartmental replacement

These indications will be used for the combined unicompartmental and patello-femoral implant device, whereby a single condyle and patello-femoral regions have been affected by one or more of these conditions. Combined Unicompartmental and Patello-Femoral implants are intended for implantation with bone cement.

The ZUK Unicompartmental Knee System is indicated for patients with:

-Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
-Previous tibial condyle or plateau fractures with loss of anatomy or function.
-Varus or valgus deformities.
-Revision of previous arthroplasty procedures.
-These devices are indicated for cemented use only.
-The ZUK Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

Technological Characteristics
The devices that make up the ZUK Select Knee System are existing devices previously cleared by the FDA. As result, much of the testing makes reference to existing information previously provided to the agency. Additional mechanical testing, Contact Area Analysis, was conducted on the subject device(s) to support the use of the components in combination.

Based on the testing, there are no new issues related to the safety and effectiveness of the subject device(s). Clinical data was not needed to support the safety and effectiveness of the subject device(s).

Substantial Equivalence Information
The ZUK Select Knee System is identical in function, identical design features, intended use, indications for use, operational principles because the parts are the identical product components cleared in previous premarket notifications listed in **Table 5-1**.

Table 5-1: Substantially Equivalent Predicates to the ZUK Select Knee System

Manufacturer	Description	Submission Number	Clearance Date
Zimmer	Zimmer Unicompartmental Knee System Vivacit-E Articular Surface	K122529	11/16/2012
Smith & Nephew, Inc.	Journey Select Knee System	K093056	12/15/2009
Smith & Nephew, Inc.	Journey Unicondylar Femoral Implant	K081351	07/24/2008
Smith & Nephew, Inc.	Patello-Femoral Knee Implant	K051086	05/31/2005
Zimmer	Zimmer Unicompartmental Knee System	K033363	01/16/2004

Conclusion
No new or modified knee implant components or device specific instruments are being introduced as a result of this filing. Because the subject device is made up of identical product components from previous premarket notifications, the subject device is substantially equivalent to the listed predicates.