July 19, 2023

Smith & Nephew, Inc.
Nikita Deshpande
Sr. Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K231448
Trade/Device Name: TANDEM Hip System
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZY, KWY
Dated: May 18, 2023
Received: May 18, 2023

Dear Nikita Deshpande:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of JointArthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231448

Device Name

TANDEM Hip System

Indications for Use *(Describe)*

The Smith & Nephew TANDEM Unipolar and Bipolar Hip System is intended for partial hip arthroplasty in skeletally mature patients. It is indicated for use in patients not suitable for total hip arthroplasty, with a non-functional femoral head due to femoral neck fracture.

The TANDEM Unipolar and Bipolar head components are intended to articulate against the natural acetabulum, which requires no use of 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.

510(k) Summary

Prepared on: 2023-07-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	1450 Brooks Road Memphis TN 38116 United States
Applicant Contact Telephone	901-825-8527
Applicant Contact	Ms. Nikita Deshpande
Applicant Contact Email	nikita.deshpande@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TANDEM Hip System
Common Name	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Classification Name	Prosthesis, Hip, Hemi-, Femoral, Metal Ball
Regulation Number	888.3360
Product Code	LZY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K896580	TANDEM UNI-POLAR Hip System	LZY
K023743	TANDEM International Bipolar Hip System	KWY
K211176	Smith & Nephew Hip System	LPH

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this traditional 510(k) is to notify FDA of Smith & Nephew's intent to request clearance for labeling updates to Smith & Nephew's TANDEM Hip System.

The TANDEM Hip Systems have been initially cleared by FDA and the information related to the clearance of these devices has been provided below:

1. TANDEM Unipolar Hip System (CoCr Heads and Taper Sleeves) – K896580 (S.E Date – 02/15/1990)
2. TANDEM INTL (International) Bipolar Hip System – K023743 Letter To File (Date – 01/21/2004)

Note: The TANDEM International Bipolar Hip System is a modified version of the TANDEM Bipolar System which was cleared for market under 510(k) submission number K023743.

The subject Smith & Nephew TANDEM Hip System devices are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared. These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

The labeling updates include changes made to the Instructions for Use (IFU), device labels, and surgical technique. The indications for use and target patient population have been limited for using the subject TANDEM Hip System devices based on available clinical and post market surveillance data. These updates have been made to support compliance to the European Medical Device Regulation

2017/745 and standardization of verbiage across Smith & Nephew's hip implants.

The TANDEM Hip System is designed to be used for hemiarthroplasty as implantation of these devices replace diseased, affected, or broken femoral head and/or neck with a prosthetic component, while keeping the natural acetabulum, or hip socket, intact. The TANDEM Hip System includes the TANDEM Unipolar Hip System and TANDEM International Bipolar Hip System. Both the systems are used for partial hip replacement procedure, in which the unipolar head or bipolar shell are designed to articulate against the host acetabular articular cartilage and replace the femoral head and/or neck during the implantation procedure. The key difference between a unipolar and a bipolar version of the TANDEM Hip System is number of rotational points that are provided – single (unipolar) or two (bipolar) – within the socket.

Materials
The TANDEM Unipolar Hip System comprises of unipolar femoral head and taper sleeve. The TANDEM Unipolar Hip System's unipolar femoral head components are manufactured using Cobalt-Chromium alloy conforming to ASTM F75 and ISO 5832-4. The Taper Sleeve components are manufactured from titanium (Ti6Al4V) alloy conforming to ASTM F1472 and ISO 5832-3. The Taper Sleeve components are also manufactured from annealed ELI (extra low interstitial) grade Titanium alloy (Ti6Al4V) conforming to ASTM F136.

The TANDEM International Bipolar Hip System is made up of several components and is manufactured from cobalt chromium (CoCr) alloy conforming to ASTM F75 and ISO 5832-4, Ultra High Molecular Weight Polyethylene (UHMWPE) conforming to ASTM F648 and ISO 5834-2, titanium (Ti6Al4V) alloy conforming to ASTM F1472 and ISO 5832-3.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Smith & Nephew TANDEM Unipolar and Bipolar Hip System is intended for partial hip arthroplasty in skeletally mature patients. It is indicated for use in patients not suitable for total hip arthroplasty, with a non-functional femoral head due to femoral neck fracture.

The TANDEM Unipolar and Bipolar head components are intended to articulate against the natural acetabulum, which requires no use of bone cement.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The purpose of this traditional 510(k) is to notify FDA of Smith & Nephew's intent to request clearance for labeling updates to Smith & Nephew's TANDEM Hip System. The labeling updates include changes to the indications for use.

The Smith & Nephew TANDEM Unipolar and International Bipolar Hip Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to the commercially available predicate devices TANDEM Unipolar Hip System (K896580, 02/15/1990) and TANDEM International Bipolar Hip System (K0237343, 01/21/2004).

The labeling updates include changes made to the Instructions for Use (IFU), device labels, and surgical technique. The indications for use and target patient population have been limited for using the subject TANDEM Hip System devices based on available clinical and post market surveillance data. These updates have been made to support compliance to the European Medical Device Regulation 2017/745 and standardization of verbiage across Smith & Nephew's hip implants.

Technological Comparison 21 CFR 807.92(a)(6)

The devices that comprise the TANDEM Unipolar and Bipolar Hip System have the same technological characteristics, including device design and material, as the predicate devices previously cleared by the FDA. Therefore, no additional testing was performed for the subject devices to support the proposed labeling updates. There are no new issues related to safety and effectiveness of the subject devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The purpose of this traditional 510(k) is to request clearance from FDA for labeling changes to the subject Smith & Nephew TANDEM Hip System implants.

The subject Smith & Nephew TANDEM Hip System devices are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared. These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

Therefore, since there are no changes to the design features, materials, or manufacturing methods of the TANDEM Hip System devices, no performance testing (bench, animal, clinical) was required.

Clinical data was not needed to support the safety and effectiveness of the subject devices.

No new or modified hip implant components are being introduced as a result of this filing. The subject devices are substantially equivalent to the previously 510(k) cleared predicate devices.