October 29, 2021

Smith & Nephew, Inc.
Leah Andre
Regulatory Affairs Specialist II
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K211512
Trade/Device Name: VISIONAIRE UK Patient Matched Cutting Guides
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX, OOG, MBH, JWH

Dear Leah Andre:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 16, 2021. Specifically, FDA is updating this SE Letter as an administrative correction. The 510(k) summary that was included in the SE package included the VISIONAIRE lateral cutting guides; however, the VISIONAIRE lateral cutting guides have been removed from the submission. The updated 510(k) summary does not include the lateral cutting guides and will be included in the SE Package.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ting Song, Ph.D., R.A.C., OHT6: Office of Orthopedic Devices, (301) 769-7677.

Sincerely,

Ting Song -S

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

September 16, 2021

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

Re: K211512
Trade/Device Name: VISIONAIRE UK Patient Matched Cutting Guides
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, OOG, MBH, JWH
Dated: August 19, 2021
Received: August 20, 2021

Dear Leah Hawkins:

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,

Ting Song -S

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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.

510(k) Number *(if known)*

K211512

Device Name
VISIONAIRE UK Patient Matched Cutting Guides

Indications for Use *(Describe)*

Smith & Nephew's VISIONAIRE UK Patient Matched Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are intended for use with the following existing Smith & Nephew, Inc. Knee Systems and their cleared indications for use:

- JOURNEY II Unicompartmental Knee (JOURNEY II UK) System

The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are intended for single use only.

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 Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	May 13, 2021
Primary Contact Person:	Leah Hawkins, Regulatory Affairs Specialist II T (901) 800-3355 M (901) 463-8447
Secondary Contact Person:	Michelle Huettner, Director, Regulatory Affairs T (901) 800-3241 M (765) 426-6070
Name of Device:	VISIONAIRE UK Patient Matched Cutting Guides
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	21 CFR 888.3520 - Knee Joint femorotibial metal/polymer non-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSX - Knee joint femorotibial metal/polymer non-constrained cemented prosthesis OOG - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. MBH - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

JWH - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Predicate Device:

Primary Predicate: Materialise PKA Guide System - K173970 (S.E. 7/6/2018)
HSX, OOG

Secondary Predicate: VISIONAIRE Patient Matched Cutting Blocks - K200826 (S.E. 4/24/2020)
JWH, MBH, OOG

Reference Device: VISIONAIRE Adaptive Guides - K170282 (S.E. 5/22/2017)
JWH, MBH, OOG

Device Description

The purpose of this Traditional 510(k) is to notify the FDA of our intent to market the Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides with the VISIONAIRE Patient Matched Technology. The VISIONAIRE Unicompartmental Knee (UK) Patient Matched Cutting Guides are to be used as patient-specific surgical instrumentation to assist in the positioning of partial knee replacement implant components intra-operatively and in guiding the marking of bone before cutting. The subject device is designed and manufactured from patient imaging data (i.e. MRI, X-Ray) using additive manufacturing of Nylon 12 material to create the patient-matched guides. The blocks achieve mechanical alignment via an intimate fit with the patient's proximal tibia or distal femur. This fit is achieved by reconstructing the patient's bony and cartilaginous anatomy from the MRI scans of the patient's knee. The VISIONAIRE UK Patient Matched Cutting Guides are intended to be used for medial femoral and tibia resections in conjunction with previously cleared Smith & Nephew JOURNEY II Unicompartmental Knee (JOURNEY II UK) System (K190085). Similar unicompartmental knee patient-specific surgical instrumentation used with JOURNEY II UK System has been previously cleared as Materialise PKA Guide System (Primary Predicate – K173970).

The VISIONAIRE UK Patient Matched Cutting Guides utilizes VISIONAIRE Patient Matched Technology to design and manufacture the patient-matched guides. As a result of this submission, the subject device will use the VISIONAIRE Patient Matched Technology process in previously cleared VISIONAIRE Patient Matched Cutting Blocks (Secondary Predicate - K200826). The only modification to the VISIONAIRE Patient Matched Technology process is the addition of VISIONAIRE UK implant options.

The VISIONAIRE UK Patient Matched Cutting Guides are a line extension to the currently marketed VISIONAIRE Adaptive Guides (Reference Device – K170282) and will utilize similar manufacturing and technological processes.

Indications for Use

Smith & Nephew's VISIONAIRE UK Patient Matched Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are intended for use with the following existing Smith & Nephew, Inc. Knee Systems and their cleared indications for use:

- JOURNEY II Unicompartmental Knee (JOURNEY II UK) System (K190085)

The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are intended for single use only.

Technological Characteristics

Smith & Nephew conducted cadaveric testing of the VISIONAIRE UK Patient Matched Cutting Guides. The results of this testing demonstrated that the patient matched cutting blocks/guides designed using the case processing applications perform equivalent to the predicate devices listed in the **Table 5.1 below**.

The associated software in order to manufacture the subject device demonstrate that there are no new issues related to the safety and effectiveness of the predicate device and the software will perform as intended. All changes are made to the non-medical device software as part of the subject device submission. There are no changes required to the previously cleared VISIONAIRE Patient Matched Cutting Blocks software (Secondary Predicate - K200826) that are involved in creating the VISIONAIRE UK Patient Matched Cutting Guides. Additional details related to the software are provided in **Section 16**.

Based on the testing within this premarket notification, there are no new issues related to the safety and effectiveness of the subject device. Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are substantially equivalent in function, equivalent design features, intended use, indications for use, operational principles, manufacturing processes, and materials as the commercially available predicate devices listed below in **Table 5.1**.

Table 5.1: Predicate Devices

Predicate Type	Manufacturer	Description	Submission Number	Clearance Date
Primary Predicate	Materialise N.V.	Materialise PKA Guide System	K173970	07/06/2018
Secondary Predicate	Smith & Nephew, Inc.	VISIONAIRE Patient Matched Cutting Blocks	K200826	4/24/2020
Reference Device	Smith & Nephew, Inc.	VISIONAIRE Adaptive Guides	K170282	05/22/2017

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the VISIONAIRE UK Patient Matched Cutting Guides. Based on the similarities to the predicate cutting blocks and guide system, cadaveric testing, and a review of the software validation testing performed, the subject device is substantially equivalent to the commercially available predicate devices listed above.