April 24, 2020

Smith&Nephew, Inc.
Brad Sheals
Regulatory Affairs Manager
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K200826
Trade/Device Name: Smith&Nephew VISIONAIRE Patient Matched Cutting Blocks
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, MBH, OOG
Dated: March 27, 2020
Received: March 30, 2020

Dear Brad 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. 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, PhD, RAC
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200826

Device Name

Smith & Nephew VISIONAIRE Patient Matched Cutting Blocks

Indications for Use *(Describe)*

Smith & Nephew's VISIONAIRE Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total 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 Patient Matched Cutting Blocks are intended for use with the following existing Smith & Nephew, Inc. Knee Systems and their cleared indications for use:

- Genesis II Knee System
- Legion Knee System
- Journey BCS Knee System
- Journey II Knee System

The Smith & Nephew VISIONAIRE Patient Matched Cutting Blocks 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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	04/07/2020
Contact Person and Address:	Brad Sheals Regulatory Affairs Manager T 901-399-6897 F 901-566-7911
Name of Device:	Smith & Nephew VISIONAIRE Patient Matched Cutting Blocks
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	21 CFR 888.3560- Knee joint patellofemorotibial polymer/metal/polymer non-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH, MBH, OOG

Device Description

The subject of this premarket notification is to seek FDA clearance of software components to be used in the design and manufacture of the VISIONAIRE Patient Matched Cutting Blocks. Patient Matched Cutting Blocks were previously cleared for market via premarket notifications- K183010. The blocks are designed utilizing the VISIONAIRE Patient Matched Technology software components and patient imaging data (MRI, X-Ray). The blocks are intended to be used as patient-specific surgical instruments to assist in the positioning of total knee replacement implant components intra-operatively and in guiding the marking of bone before cutting.

Intended Use

Smith & Nephew's VISIONAIRE Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total 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 Patient Matched Cutting Blocks are intended for use with the following existing Smith & Nephew, Inc. Knee Systems and their cleared indications for use:

- Genesis II Knee System
- Legion Knee System
- Journey BCS Knee System
- Journey II Knee System

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

Technological Characteristics

No new mechanical testing was performed. No implants or new blocks are being introduced in this premarket notification. There are no changes to the block design, packaging, material composition or manufacturing of Smith & Nephew VISIONAIRE Patient Matched Cutting Blocks as a result of these changes described in the premarket notification. Clinical data was not needed to support the safety and effectiveness of the subject device(s). The following technological difference exists between the subject device and predicate device, which is related to the manufacturing and design process (e.g. The use of an additional X-ray measurement tool and removal of MDDS-Non Devices as defined in Section 520 (o)(1)(D)).

Software verification and validation testing was completed in line with FDA's guidance document entitled, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," dated January 11, 2002. A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject device and the software will perform as intended. Per the FDA's recommendations, the VISIONAIRE Patient Matched Technology software components for this device were considered as a "major" level of concern, since a failure in the software could directly result in serious injury or death to the patient or operator.

Based on the documentation 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 Patient Matched Cutting Blocks are identical in function, equivalent design features, intended use, indications for use, operational principles, manufacturing processes, and materials as the predicate device- Patient Matched Cutting Blocks (K183010, S.E. 11/28/2018).

Conclusion

This premarket notification is being submitted to request clearance of the subject Smith & Nephew VISIONAIRE Patient Matched Cutting Blocks. Based on the similarities to the predicate cutting blocks and a review of the software testing performed, the subject device is substantially equivalent to the predicate device- Patient Matched Cutting Blocks (K183010, S.E. 11/28/2018).