



January 10, 2018

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

Re: K172336

Trade/Device Name: Smith & Nephew 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: July 26, 2017

Received: August 2, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K172336

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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Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Date of Summary: July 26, 2017

Contact Person and Address: Brad Sheals
Principal Regulatory Affairs Specialist
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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 a software component to be used in the design and manufacture of the VISIONAIRE Patient Matched Cutting Blocks. Also within this notification is an extension of the subject device's shelf life. Patient Matched Cutting Blocks were previously cleared for market via premarket notifications- K082358, K130708 and K170282.

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).

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.

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 (K082358, 11/25/2008, K130708, S.E. 02/28/2014 and K170282, S.E. 05/22/2017).

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 testing performed, the subject device is substantially equivalent to the predicate device- Patient Matched Cutting Blocks (K082358, 11/25/2008; K130708, S.E. 02/28/2014 and K170282, S.E. 05/22/2017).