July 20, 2020

Smith & Nephew
Kathleen Solomon
Principal Regulatory Affairs Specialist
150 Minuteman Rd
Andover, Massachusetts 01810

Re: K201349
Trade/Device Name: Smith+Nephew Arthroscopes
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: May 20, 2020
Received: May 21, 2020

Dear Ms. Solomon:

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,

Laura C. Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K201349

Device Name
Smith+Nephew Arthroscopes

Indications for Use *(Describe)*

The Smith+Nephew Arthroscopes is indicated to provide illumination and visualization in:

• Diagnostic and Operative arthroscopic procedures for the hip, knee, shoulder, wrist, ankle, elbow, and feet.

In addition, Smith+Nephew 4 mm diameter rigid arthroscopes are indicated to provide illumination and visualization in the removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810
Massachusetts, USA

T: + 1 978 749 1000
T: + 1 800 343 8386 (USA toll free)
www.smith-nephew.com

Smith+Nephew

K201349

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew: Smith+Nephew Arthroscopes

Date Prepared: **July 20, 2020**

A. Submitter's Name:

Smith+Nephew, Inc., Endoscopy Division

150 Minuteman Road, Andover MA. 01810

B. Company Contact:

Kathleen Solomon

Principal Regulatory Affairs Specialist

T 978-749-1605

C. Device Name

Trade Name: Smith+Nephew Arthroscopes

Common Name: Arthroscopes

Classification Name: Arthroscopes per 888.1100

Regulatory class: II

Product Code: HRX

D. Predicate Devices

The Smith+Nephew Arthroscope are substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution: Henke Sass Wolf Arthroscopes, K080560.

E. Description of Device

The proposed Smith+Nephew 4KO Direct View/Video Arthroscopes are a line extension to the previously cleared K971253 and are surgical instruments used for illumination and visualization of surgical sites within articular cavities, body cavities, hollow organs and canals.

The Arthroscopes are designed with various angle specifications for directions of view and working lengths for access to various locations. The Arthroscopes are shipped non-sterile and must be cleaned, inspected and sterilized prior to each use. Both designs consist of a long tube containing a series of rod lenses that work to transfer the image of the patient's anatomy, through an associated visualization camera system, to a central monitor for clinical use in treatment.

The direct view scopes require attachment to an endocoupler and the VideoEndoscopes are attached to a Smith+Nephew C-Mount camera head.

Illumination is provided through a bundle of optical fibers internal to the Endoscope that transmits light from an external source to illuminate the image.

F. Intended Use

The Smith+Nephew Arthroscopes are intended to provide illumination and visualization in diagnostic and operative arthroscopic procedures.

Indication for Use:

The Smith+Nephew Arthroscopes is indicated to provide illumination and visualization in:

• Diagnostic and Operative arthroscopic procedures for the hip, knee, shoulder, wrist, ankle, elbow, and feet.

In addition, Smith+Nephew 4 mm diameter rigid arthroscopes are indicated to provide illumination and visualization in the removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

G. Comparison of Technological Characteristics

The S+N Arthroscopes maintain the following similarities as the predicate devices cleared in K080560. In that:

- The proposed and predicate devices have similar indications for use/intended use.
- Both the proposed and predicate devices utilize the same principle of operation and incorporate the same basic design
- Incorporate the same materials

The difference in the new Smith+Nephew Arthroscopes as compared to the predicate devices are:

- The new Smith+Nephew 4KO Arthroscopes have an improved optical design in order to provide 4K resolution capabilities for sharper visualization compared to the predicate HD.
- The new Smith + Nephew VideoArthroscopes have an updated focusing mechanism design with similar shape and smaller focus ring size comparing to HD endoscopes

The differences between the proposed and predicate devices do not constitute a new Intended use, there are no major differences in technological characteristics and does not introduce new risks or questions of safety or effectiveness.

H. Performance Data

Performance Testing demonstrates that the Smith+Nephew Arthroscopes have met the performance specifications:

- Optical Performance
- Leakage Integrity
- Electrical Safety Testing
- Electromagnetic Compatibility
- Cleaning Validation
- Sterilization Validation
- Biocompatibility

Smith+Nephew validated cleaning and sterilization of the Arthroscopes against the requirement of AAMI TIR 12:2010 and AAMI TIR 30:2011 and all acceptance criteria were met. Biocompatibility assessment of the Arthroscopes against the requirements per ISO 10993-1:2018 and all acceptance criteria were met.

Therefore, the Arthroscopes are considered substantially equivalent the currently marketed predicate.

G. Conclusion:

The Smith+Nephew Arthroscopes met all specified criteria and did not raise new safety or effectiveness questions. The substantial equivalence of the modified device is based on the same fundamental technology. Based on the similarities to the predicate and the performance data, the S+N Arthroscopes are considered substantially equivalent to the predicate K080560.