July 17, 2020

Smith & Nephew Inc., Endoscopy Division
Janice Haselton
Principal Regulatory Affairs Specialist
150 Minuteman Rd
Andover, Massachusetts 01810

Re: K201198
Trade/Device Name: Smith & Nephew Laparoscopes (4KO, Autoclavable), Smith & Nephew Bariactric Laparoscopes (4KO, Autoclavable)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 20, 2020
Received: May 21, 2020

Dear Janice Haselton:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K201198

Device Name
Smith & Nephew Laparoscopes

Indications for Use *(Describe)*

The Smith & Nephew Laparoscopes are indicated for use in illumination and visualization to surgical sites within the body. This includes, but not limited to uses such as gallbladder and appendix removal, hernia repair, and examination of the abdominal cavity, appendix, gallbladder and Liver.

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

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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)*
K201198

Device Name
Smith & Nephew Bariatric Laparoscopes

Indications for Use *(Describe)*

Smith & Nephew Bariatric Laparoscopes are indicated for illumination and visualization to surgical sites within the body. This includes, but not limited to uses such as gallbladder and appendix removal, hernia repair, and examination of the abdominal cavity, appendix, gallbladder and Liver.

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)

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K201198

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 Endoscopes (Laparoscopes and Bariatric Laparoscope)

Date Prepared: **July 16, 2020**

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road, Andover MA. 01810

B. Company Contact:

Janice Haselton

Principal Regulatory Affairs Specialist

T 978-749-1494

C. Device Name

Trade Name: Smith & Nephew Endoscopes

Common Name: Laparoscopes

Classification Name: Endoscopes and Accessories per 876.1500

Regulatory class: II

Product Code: GCJ

D. Predicate Devices

The Smith & Nephew Laparoscopes and Bariatric Laparoscopes are substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Henke Sass Wolf Laparoscopes and Laparoscopes cleared in K941541 (Laparoscopes) and K050163 (Bariatric Laparoscopes).

E. Device Description

The proposed Smith+Nephew 4KO Direct View/Video Laparoscopes are surgical instruments used for illumination and visualization of surgical sites within articular cavities, body cavities, hollow organs and canals. A Laparoscope is a medical optical instrument that is intended for visualization of the insides of the human body by inserting the instrument into a natural or artificial opening.

The Laparoscopes are designed with various angle specifications for directions of view and working lengths for access to various locations. The design 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/Indications for Use

Intended Use

The Smith & Nephew Laparoscopes are intended to be used in general laparoscopic surgery for access to internal structures.

Indications for Use

Smith & Nephew Laparoscopes are indicated for use in for illumination and visualization to surgical sites within the body. This includes, but not limited to uses such as gallbladder and appendix removal, hernia repair, and examination of the abdominal cavity, appendix, gallbladder, and Liver.

Bariatric Laparoscopes

Intended Use

Smith & Nephew Bariatric Laparoscopes are intended to be used in general laparoscopic surgery for access to internal structures in morbidly obese segments of the patient population.

Indications for Use

Smith & Nephew Bariatric Laparoscopes are indicated for illumination and visualization to surgical sites within the body. This includes, but not limited to uses such as gallbladder and appendix removal, hernia repair, appendix, gallbladder and Liver.

G. Comparison of Technological Characteristics

The S&N Laparoscopes maintain the following similarities to what was previously cleared in K941541 (Laparoscopes) and K050163 (Bariatric Laparoscopes). 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 Endoscopes as compared to the predicate devices are:

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

The differences that the Smith & Nephew Laparoscopes have met the performance specifications and therefore are substantially equivalent to the predicate device cleared in K941514 and K050163.

H. Performance Testing

Performance Testing-Bench

The following testing was performed on the Laparoscopes to demonstrate that they meet the established performance specifications and therefore, are substantially equivalent to the predicate device cleared in K941541 (Laparoscopes) and K050163 (Bariatric Laparoscopes).

- Optical Performance
- Leakage Integrity Testing
- Electrical Safety Testing

- Electromagnetic Compatibility

I. Conclusion

The Smith & Nephew Laparoscopes met all specified criteria and did not raise new safety or effectiveness questions. The substantial equivalence of the modified devices is based on similar indications for use, same principle of operation and same basic design. Based on the similarities to the predicate devices and performance data, the Smith+Nephew Laparoscopes are substantial equivalent to its predicates K941541 and K050163.