Smith & Nephew
Ms. Janice Haselton
Principal Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

May 21, 2019

Re: K190367
Trade/Device Name: Smith & Nephew Tablet Application
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: QGY
Dated: February 12, 2019
Received: February 22, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

For Jennifer Stevenson,
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190367

Device Name
Tablet Application

Indications for Use *(Describe)*

The Smith & Nephew Tablet Application is indicated for wireless control of compatible Smith & Nephew passive surgical and endoscopic devices including camera/camera control unit and patient information system.

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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"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."

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

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We are smith&nephew

SECTION IV

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 Tablet Application

Date Prepared: February 5, 2019

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

F 978-749-1407

C. Device Name

Trade Name: Tablet Application

Common Name: APP

Classification Name: Mobile / tablet software application to control settings of surgical and endoscopic camera 876.1500

Regulatory class: 2

Product Code: QGY

D. Predicate Devices

The Tablet Application is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution:

Smith & Nephew LENS Integrated System APP cleared in K153606

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

T 978-749-1000
F 978-749-1443
www.smith-nephew.com

E. Description of Device

The Tablet Application acts as a tool to remotely capture still and motion pictures, patient file management, and limited redundant control of medical devices. The Tablet Application currently supports the LENS Integrated System and Integration Broker.

F. Intended Use/Indications for Use:

The Smith & Nephew Tablet Application is indicated for wireless control of compatible Smith & Nephew passive surgical and endoscopic devices including camera/camera control unit and patient information system.

H. Comparison of Technological Characteristics

The modified Smith & Nephew Tablet Application has the following similarities as the predicate device cleared in K151326. In that:

- Utilizes the same principle of operation and fundamental scientific technology
- Incorporates the same basic software design

The differences between the currently cleared device and the proposed device are an expanded Intended Use and Indication for Use.

I. Performance Data

Testing demonstrated that the Tablet Application has met the performance specifications and therefore, is substantially equivalent to the predicate device cleared in K151326.

The following performance data and validations were conducted:

- Software Verification and Validation

Conclusion:

The Smith & Nephew Tablet Application met all specified criteria and did not raise new safety or effectiveness questions. The substantial equivalence of the modified device is based on fundamental technology including software design and principles. Based on the similarities to the predicate and the performance data, the Smith & Nephew Tablet Application is substantially equivalent to its predicate (K151326).