September 6, 2022

Smith+Nephew
Kathleen Solomon
Principal Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K221929/S001
Trade/Device Name: Smith+Nephew INTELLIO Tablet
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODA
Dated: June 30, 2022
Received: July 1, 2022

Dear Kathleen 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,

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221929

Device Name
Smith+Nephew INTELLIO Tablet

Indications for Use *(Describe)*
The Smith+Nephew INTELLIO Tablet is indicated for use to provide wired or wireless remote control of Smith+Nephew compatible surgical and endoscopic devices within the operating room including camera/camera control unit, patient information system, mechanical resection system, fluid management system and RF coblation system. These controls consist of adjusting parameter settings 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.

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

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 INTELLIO Tablet

Date Prepared: **June 30, 2022**

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

E Kathleen.solomon@smith-nephew.com

C. Device Name

Trade Name: Smith+Nephew INTELLIO Tablet

Common Name: Tablet Application

Classification Name: Endoscopes and Accessories, 876.1500

Regulatory class: II

Product Code: ODA

D. Predicate Devices

The Smith+Nephew INTELLIO Tablet presented in this submission is equivalent in intended use and fundamental scientific technology to the following legally marketed device currently in commercial distribution: Smith+Nephew Tablet Application cleared in K203566.

E. Description of Device

The INTELLIO Tablet application software is pre-installed upon a medical grade tablet that is used with compatible Smith + Nephew surgical and endoscopic devices. The device allows for control of parameters within the operating room, including camera/camera control system, patient information system, mechanical resection system, Fluid Management system and RF Coblation system. The device also connects to the MY.INTELLIO™ cloud and provides access to medical device status, settings,

images/videos, and reports before, during and after surgical procedures. Additionally, software updates are manually downloaded from the MY.INTELLIO cloud account via secured link and can be installed via the administrator account

The device is able to set parameters remotely for the Fluid management pumps, Mechanical Resection controller and RF Coblation controller by connecting to the Wifi connect device either separate (LINK box) or integrated with the individual pump or controller. It also provides a secondary control mechanism for all of these devices forming a connected system. The primary control for setting parameters are on the individual devices.

F. Intended Use

Indication for Use:

The Smith+Nephew Tablet Application is indicated for use to provide wired or wireless remote control of Smith+Nephew compatible surgical and endoscopic devices within the operating room including camera/camera control unit, patient information system, mechanical resection system, fluid management system and RF coblation system. These controls consist of adjusting parameter settings only.

G. Comparison of Technological Characteristics

The Smith+Nephew Tablet Application has the following similarities as the predicate device, Smith+Nephew Tablet Application, cleared in K203566. In that:

- The proposed and predicate devices have similar indications for use/intended use.
- Both the predicate and proposed utilizes the same principle of operation and fundamental scientific technology
- Both the predicate and proposed devices allow for control of parameters within the operating room.

The differences between the proposed INTELLIO Tablet and the predicate device S+N Tablet Application are:

- The Intellio software application will be provided on an Android platform. The predicate platform is an Apple iOS.
- The Intellio software application is pre-installed on medial grade tablet. The predicate is downloaded from Apple store onto the surgeon's iPad.

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

H. Performance Data

Testing demonstrated that the Smith+Nephew INTELLIO Tablet has met the performance specifications, required Cybersecurity testing and therefore, is substantially equivalent to the predicate device cleared in K203566.

The following testing was performed:

- Physical Verification
- Software Verification and Validation
- Emissions and Immunity Testing
- Electrical Safety Testing

G. Conclusion:

The Smith+Nephew INTELLIO Tablet has met all specified criteria and does not raise new safety or effectiveness questions. The substantial equivalence of the modified device is based on similar indications for use, principal of operation and fundamental technology. Based on the similarities to the predicate device and the performance data, the Smith+Nephew INTELLIO Tablet Application is substantially equivalent to its predicate device cleared in K203566.