October 20, 2022

Smith and Nephew, Inc.
Renesha Srivastava
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

Re: K221740
Trade/Device Name: Smith & Nephew Intellio 4k Camera Control Unit, Network Enabled (72205447), Smith & Nephew Intellio 4k Camera Control Unit, Non-network Enabled (72205448)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 13, 2022
Received: June 15, 2022

Dear Renesha Srivastava:

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,

Jiantang Wang
Acting 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)*
K221740

Device Name
SMITH & NEPHEW INTELLIO 4K CAMERA CONTROL UNIT, NETWORK ENABLED (72205447), SMITH & NEPHEW INTELLIO 4K CAMERA CONTROL UNIT, NON-NETWORK ENABLED (72205448)

Indications for Use *(Describe)*
The Smith+Nephew INTELLIO 4K CCU is intended for use in diagnostic, and operative endoscopic surgical procedures, including but not limited to, for example: orthopedic procedures, laparoscopic procedures, and otolaryngology (sinuscopic) procedures when used with an appropriately indicated endoscope.

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.

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INTELLIO 4K CAMERA CONTROL UNIT
SMITH AND NEPHEW INC.

510K SUMMARY

Pursuant to Title 21 of Code of Federal Regulations, Subchapter H, section 807.92(a), the Traditional 510K Summary to seek clearance for the device INTELLIO 4K Camera Control Unit (CCU) is stated as follows:

1) **Submitter**: Smith & Nephew Inc.
   Address: 150 Minuteman Road, Andover, Massachusetts, USA – 01810
   Telephone Number: +1(978) 749-1000
   Contact Person: Renesha Srivastava
   Date: 10/17/2022

2) **Device:** SMITH & NEPHEW INTELLIO 4K CAMERA CONTROL UNIT
   Trade Name and/or Proprietary Name: INTELLIO 4K Camera Control unit
   Common Name/Usual Name: Camera Control Unit
   Regulation and Product Code: 876.1500 / GCJ

3) **Predicate Device:** SMITH & NEPHEW LENS 4K SYSTEM
   The INTELLIO 4K CCU is substantially equivalent to the Smith and Nephew LENS 4K System Camera Control Unit, cleared by the FDA under the Premarket Notification K191177. The INTELLIO 4K CCU has an updated Graphical User Interface (GUI) and can be operated by an optional accessory, the INTELLIO Tablet. The Wi-Fi network that can be supported by the device includes dual bandwidth of 2.4 GHz and 5.0 GHz.
   Intended Use of INTELLIO 4K CCU: The Smith&Nephew INTELLIO 4K CCU is intended for illumination and visualization of endoscopic surgical procedures.
   Indications for Use for INTELLIO 4K CCU: The Smith+Nephew INTELLIO 4K CCU is intended for use in diagnostic, and operative endoscopic surgical procedures, including but not limited to, for example: orthopedic procedures, laparoscopic procedures, and otolaryngology (sinuscopic) procedures when used with an appropriately indicated endoscope.
   Similarities between the subject and predicate devices:

   a) Both the devices have similar Intended Use
   b) Both the devices have similar Indications for Use
   c) Both the devices have similar accessory input and output ports

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d) Both the devices have the same integrated light source and light guide connector
e) Both the devices are compatible with the same LENS 4K Camera Head, used as an accessory, and cleared by the FDA (K191177)
f) The display resolution for both the devices are same
g) Both the devices can operate with the same electrical power input

Differences between the subject and the predicate device:

a) The INTELLIO 4K CCU supports an additional feature to enable a lavage trigger, that would allow the washing away of fluid from the surgical area.
b) The INTELLIO 4K CCU can operate on both 2.4 GHz and 5.0 GHz Wi-Fi enabled network system, as compared to the Predicate that can operate only on 2.4 GHz Wi-Fi enabled network system.
c) The INTELLIO 4K CCU has a reorganized enclosure and front panel, with mechanical buttons and an updated Graphical User Interface (GUI)
d) The INTELLIO 4K CCU can be controlled by the optional INTELLIO Tablet, which was not a feature on the predicate device
e) The INTELLIO 4K CCU has an updated chassis with a difference in overall size dimension and cover design (top cover) as compared to the Predicate device.

Device Description Summary: The Smith & Nephew INTELLIO 4K CCU is a part of the Smith & Nephew visualization system. It is an all-in-one 4K imaging console and LED light source designed for endoscopic surgical procedures. The CCU is compatible with the LENS 4K Camera Head. The functional system level architecture of this device demonstrates multiple functions, that includes the illumination of surgical space and capturing of raw imaging data from the camera sensors. It also processes the imaging data and transfers it to the attached monitor for display. Apart from capturing still images and video during the procedure, the device also adjusts the visualization settings (brightness, line enhancement, color saturation/hue and image zoom) and allows optional communication to a medical tablet to facilitate centralized control of all tower devices from the tablet. The device contains of a Wi-Fi board that supports communication frequency of 2.4 GHz and 5.0 GHz. The device uses a LED light engine to illuminate the surgical space. The User Interface (UI) consists of buttons and LEDs that can be accessed on the front panel, which also contain the ports for camera head connector and USB slots for medical tablet and flash drive.

Non-Clinical Performance Data: The following nonclinical tests were submitted and relied on in this premarket notification submission for a determination of substantial equivalence. Testing identified in this summary has passed all acceptance criteria established by the predicate device, where applicable.

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The following bench tests have been submitted with the 510K application:

- Shock and Vibration Tests
- EMI/EMC Test Report
- Safety Test Report
- Packaging Design Verification Test Report

Clinical Performance Data: Clinical testing was not necessary for the determination of substantial equivalence.

Sterilization and Shelf Life

The INTELLIO 4K CCU is packaged in a double walled corrugated cardboard box with two endcaps that fit around the ends of the CCU. Shelf-Life for the Smith & Nephew INTELLIO 4K CCU is not applicable as the device is distributed non-sterile. Additionally, it's performance and materials do not degrade over the lifetime of the device.

Conclusion: The submission demonstrates that (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed device is at least as safe and effective as the predicate. It is concluded that the information included in this summary supports substantial equivalence.