May 13, 2025

Intuitive Surgical, Inc.
Kunal Gunjal
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K250786
Trade/Device Name: SP Endoscope, 0 (430600)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: March 13, 2025
Received: March 14, 2025

Dear Kunal Gunjal:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.05.13 11:19:17 -04'00'

Mark Trumbore Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	
Please provide the device trade name(s).	
SP Endoscope, 0° (430600)	
Please provide your Indications for Use below.	
The da Vinci SP Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci SP Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, using near-infrared imaging.	
Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Kunal Gunjal Senior Regulatory Affairs Specialist Email: Kunal.Gunjal@intusurg.com
Date Summary Prepared:	March 12, 2025
Trade Name:	SP Endoscope, 0°
Common Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	K212101 (*EndoWrist* SP Camera, 0°, PN 430077)

Device Description

The *da Vinci SP* Firefly Imaging System is a fully integrated, adjunct imaging system for the *da Vinci SP* Surgical System. The *da Vinci SP* Surgical System is a robotic-assisted surgical device (RASD) that is designed to enable complex surgery using a minimally invasive approach. The system consists of three major subsystems: the Surgeon Console, the Vision Cart, and the Patient Cart.

The *da Vinci SP* Firefly Imaging System consists of the following components of the *da Vinci SP* Surgical System (refer to ***Figure 1***):

- the *Endoscope Controller (light source)* on the Vision Cart
- the *SP Endoscope, 0° (subject device)*, which is installed on the Patient Cart

The *Endoscope Controller* provides a light source, either visible light or a near-infrared (NIR) excitation laser.

The *Endoscope* transmits visible light or NIR light from the Endoscope Controller via optical fibers to illuminate the surgical site. The stereoscopic camera at the Endoscope tip images the surgical site in either visible light mode or fluorescence imaging mode.

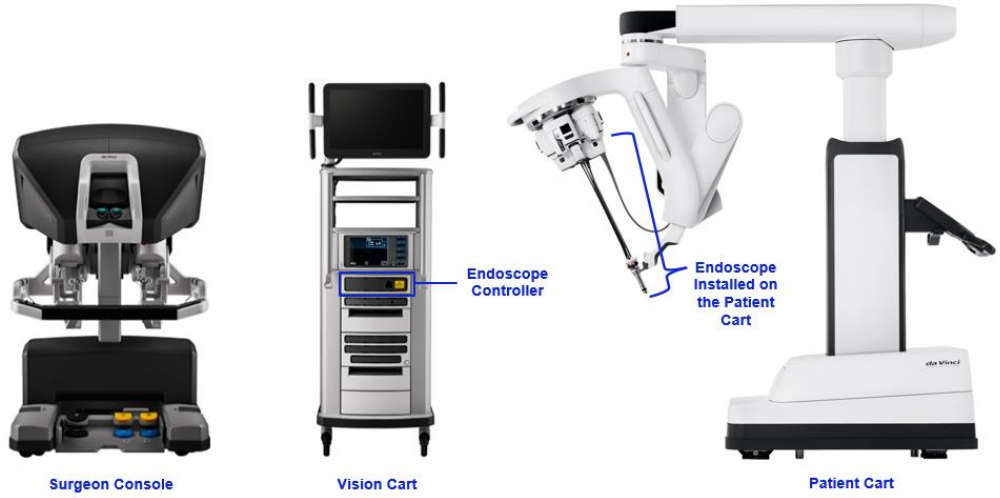

Figure 1.: Components of the da Vinci SP Firefly Imaging System within the da Vinci SP Surgical System

Indications for Use:

The *da Vinci SP* Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci SP* Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, using near-infrared imaging.

Intended Use:

The SP Endoscope, 0° is intended to provide stereoscopic imaging enabling surgeons to perform minimally invasive endoscopic surgery with the da Vinci SP system. The endoscope supports standard visible light color imaging and near-infrared fluorescence imaging.

Comparison of Predicate and Subject Device (*SP Endoscope, 0°*)

Table 2 below includes a comparison of the subject device (*SP Endoscope, 0°, PN 430600*) and the predicate device (*EndoWrist SP* Camera, 0°, *PN 430077, cleared via K212101)*.

Design changes were made to the *subject SP Endoscope (PN 430600)* relative to the predicate *EndoWrist SP* Camera, 0° (*PN 430077, cleared via K212101)*, to support increased number of lives (clinical uses).

Differences in the ***Characteristics*** as noted in this substantial equivalence comparison table is marked by ***GREYING OUT*** the specific rows. Additionally, any differences in the specific characteristics within these rows are ***BOLDED***.

Table 2: Comparison of Predicate and Subject Device (da Vinci SP Endoscope)

Characteristic	**Subject Device** *SP Endoscope, 0°*	**Predicate Device** *EndoWrist SP* Camera, 0° (K212101)
Manufacturer	Intuitive Surgical, Inc.	**IDENTICAL** to the subject device
Trade Name	*SP Endoscope, 0°*	***EndoWrist SP* Camera**, 0°
Model #	**430600**	**430077**
Common Name	Endoscope and accessories	**IDENTICAL** to the subject device
Regulation Number	21 CFR 876.1500	**IDENTICAL** to the subject device
Product Code	NAY	**IDENTICAL** to the subject device
Device Classification	Class II	**IDENTICAL** to the subject device
Classification Advisory Committee	General and Plastic Surgery	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *SP Endoscope, 0°*	**Predicate Device** *EndoWrist SP* Camera, 0° (K212101)
System Compatibility	Compatible with the ***SP1098 system***	**IDENTICAL** to the subject device
Indications for Use	The da Vinci SP Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci SP Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, using near-infrared imaging.	**IDENTICAL** to the subject device
Intended Use	The SP Endoscope, 0° is intended to provide stereoscopic imaging enabling surgeons to perform minimally invasive endoscopic surgery with the da Vinci SP system. The endoscope supports standard visible light color imaging and near-infrared fluorescence imaging.	The ***EndoWrist*** SP Endoscope, 0° is intended to provide stereoscopic imaging enabling surgeons to perform minimally invasive endoscopic surgery with the da Vinci SP system. The endoscope supports standard visible light color imaging and near-infrared fluorescence imaging.
Prescription use	Prescription/Physician use only	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *SP Endoscope, 0°*	**Predicate Device** *EndoWrist SP* Camera, 0° (K212101)
Where used (hospital, home, ambulance, etc)	Hospital	**IDENTICAL** to the subject device
Number of Lives and Reprocessing Cycles	**Number of Lives: 50** **Number of Reprocessing Cycles: 60**	**Number of Lives: 33** **Number of Reprocessing Cycles: 40**
Compatible System and Accessories	**Compatible with the following system and accessories:** ○ da Vinci SP Firefly Imaging System (K212101) ○ SP Camera Sheath (K173906)	**IDENTICAL** to the subject device
Biocompatibility	All patient-contacting materials are biocompatible per ISO 10993-1	**IDENTICAL** to the subject device
Sterilization Method	Steam Sterilization	**IDENTICAL** to the subject device
Sterility / Disposable or Multiple use	Multiple use	**IDENTICAL** to the subject device
Cleaning and Disinfection Method	Manual Cleaning Process and Thermal Disinfection	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *SP Endoscope, 0°*	**Predicate Device** *EndoWrist SP* Camera, 0° (K212101)
Packaging	Non-sterile packaging, reusable	**IDENTICAL** to the subject device

Performance Data:

The *subject device (SP Endoscope, PN 430600)* underwent a series of tests to evaluate the impact of the modifications made to the device. Testing included design verification, reliability testing, cleaning validation, transit verification, biocompatibility, design validation, and Electromagnetic Compatibility **(**EMC) testing. The successful completion of testing demonstrated that the *subject device (SP Endoscope, PN 430600)* design outputs meet the design inputs, and the design validation validated that the user needs are met. The subject device is substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness than the predicate device.

Design Verification

Bench testing was performed to verify that the functional design outputs met the functional design inputs. The design verification in this section addressed the following:

- Design Properties
- Range of Motion
- PSC Interaction
- Optical Performance
- Electrical Properties
- Firefly
- Mechanical requirements (Crimp Strength, Window Strength, Extended Illumination, Tip Durability, and Manifold Air Permeability)

Reliability Testing

Reliability Testing was performed to ensure that subject device, *SP Endoscope (PN 430600)* is not adversely affected by the increased number of lives (uses) and reprocessing cycles.

Cleaning Validation

Cleaning Validation was performed to validate the efficacy of the manual cleaning process in accordance with the following standards and guidance documents:

- FDA Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*, document issued on: March 17, 2015 (Amended on June 9, 2017).
- AAMI ST98:2022, Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices.
- AAMI TIR 12:2020, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
- AAMI TIR 30: 2011/(R)2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- ISO 17664-1:2022, Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices.

The *subject device (SP Endoscope, PN 430600)* successfully met the acceptance criteria for all markers and the test results demonstrate that the subject device can be cleaned using the manual cleaning process.

Transit Verification Testing

Transit Verification Testing was performed in accordance with *ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems.* The *subject device, (SP Endoscope, PN 430600)* met all the acceptance criteria and the test results demonstrate that the subject device has been validated for use within the shipping and distribution environment.

Biocompatibility

Biocompatibility testing was completed in accordance with the following standards and guidance documents:

- FDA Guidance: Use of International Standard ISO-10993, *"Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"*, document issued on September 8th, 2023
- ISO 10993-1:2018, Biological evaluation of medical devices

The *subject device, (SP Endoscope, PN 430600)* met all acceptance criteria for biocompatibility testing. The Biological Safety Assessment for the device materials determined that there was negligible risk to patient safety under its intended use. Therefore, the subject device met the safety and biocompatibility requirements per ISO 10993-1.

Design Validation

Simulated clinical use testing was performed to validate that the product specifications meet the user's needs and intended use.

EMC Testing

Electromagnetic Compatibility (EMC) testing was performed on the *SP1098 System* (*which includes the subject device, SP Endoscope PN 430600*) in accordance with *IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*. The test results demonstrate that the subject device meets the applicable requirements within this standard.

Conclusion:

Based on the intended use, indications for use, technological characteristics and performance data, the *subject device**, SP Endoscope, 0° (PN 430600)*** is substantially equivalent to the *predicate device* ***(EndoWrist SP Camera, 0°, PN 430077, cleared via K212101)***.