



August 29, 2025

Intuitive Surgical, Inc.
Amrit Rangan
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K251324

Trade/Device Name: da Vinci SP Surgical System (SP1098)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: July 28, 2025
Received: July 28, 2025

Dear Amrit Rangan:

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: 2025.08.29
11:58:30 -04'00'

Mark Trumbore 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

Indications for Use

510(k) Number (if known)

K251324

Device Name

da Vinci SP Surgical System (SP1098)

Indications for Use (Describe)

da Vinci SP Surgical System, Model SP1098:

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci SP Surgical System, Model SP1098) is intended to assist in the accurate control of Intuitive Surgical SP Instruments during urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

da Vinci SP Instruments:

Intuitive Surgical da Vinci SP Instruments are controlled by the da Vinci SP Surgical System, Model SP1098, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. The system is indicated for urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

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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510(k) Summary (21 CFR § 807.92)**I. SUBMITTER INFORMATION**

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Amrit Rangan
Senior Regulatory Affairs Specialist
Phone Number: 949-690-8799
Email: amrit.jaggi@intusurg.com

Date Summary Prepared: August 29, 2025

II. SUBMITTER INFORMATION

Trade Name: da Vinci SP Surgical System

Common Name: Endoscopes and accessories

Classification Name: System, Surgical, Computer Controlled Instrument (876.1500)

Regulatory Class: Class II

Product Code: NAY (System, Surgical, Computer Controlled Instrument)

Submission Type: Traditional 510(k)

III. PREDICATE DEVICE INFORMATION

Predicate Device: da Vinci SP Surgical System (K242318)

IV. Device Description

The da Vinci SP Surgical System, Model SP1098, is a software-controlled, electro-mechanical systems designed to enable complex surgery using a minimally invasive approach. The systems consist of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and are used with an endoscope, instruments, and accessories.

Indications for Use

da Vinci SP Surgical System, Model SP1098:

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci SP Surgical System, Model SP1098) is intended to assist in the accurate control of Intuitive Surgical SP Instruments during urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

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Comparison of Indications for Use Statement

The indications for use are identical between the predicate and subject device.

Comparison of Technological Characteristics

The subject da Vinci SP Surgical System, Model SP1098, is technologically similar to its predicate device. The technological differences that are the basis for this submission are limited to the updated system software for modifications to Adjust Mode while using an SP SureForm 45 Stapler and insertion jump detection algorithm for the SP SureForm 45 Stapler.

Non-Clinical Testing Summary and Conclusion

Software verification and validation have been conducted at the unit, integration, and system level to confirm that the subject devices continue to meet design requirements and user needs. Software documentation has been provided in accordance with FDA Guidance Content of Premarket Submissions for Device Software Functions, issued on June 14, 2023.

Human Factors Evaluation including usability validation has been conducted to demonstrate safety and effectiveness of the subject device. The results of this validation concluded that the subject device continues to be safe and effective for its intended use, by its intended users, and in its intended use environment. Human Factors documentation has been provided in accordance with FDA Draft Guidance Content of Human Factors Information in Medical Device Marketing Submissions issued on December 9, 2022 and FDA Guidance Document Applying Human Factors and Usability Engineering to Medical Devices issued on February 3, 2016.

Based on the intended use, indications for use, technological characteristics, and non-clinical data, the subject da Vinci SP Surgical System, Model SP1098 is substantially equivalent to and is as safe, as effective, and performs as well as its predicate device.