



September 10, 2025

Intuitive Surgical Inc.
Manjunath Ramappa Bisalehalli
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K251817

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: June 12, 2025
Received: June 13, 2025

Dear Manjunath Ramappa Bisalehalli:

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: 2025.09.10
15:53:54 -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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251817

Please provide the device trade name(s).

da Vinci SP Surgical System (SP1098)

Please provide your Indications for Use below.

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 EndoWrist 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.

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)

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Intuitive Surgical Inc.
Applicant Address	1266 Kifer Road Sunnyvale CA 94086 United States
Applicant Contact Telephone	4122984604
Applicant Contact	Mr. Manjunath Ramappa Bisalehalli
Applicant Contact Email	manjun.ramappabisalehalli@intusurg.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	da Vinci SP Surgical System (SP1098)
Common Name	Endoscope and accessories
Classification Name	System, Surgical, Computer Controlled Instrument
Regulation Number	876.1500
Product Code(s)	NAY

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243714	da Vinci SP Surgical System	NAY

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The da Vinci SP Surgical System is a robotically-assisted surgical device that is designed to enable complex surgery using a minimally-invasive approach. The system consists of three major subsystems: a Surgeon Console, a Vision Cart, and a Patient Cart.

At the Surgeon Console, the surgeon controls all movement of the instruments and endoscope by using two hand controls and a set of foot pedals. The surgeon views the live endoscope image on a three-dimensional (3D) viewer, which provides a view of patient anatomy and instrumentation, along with icons and other user interface features.

The Vision Cart includes supporting electronic equipment, such as the endoscope light source, video and image processing, and the networking hardware. The Vision Cart also has a touchscreen to view the endoscope image and adjust system settings.

The Patient Cart is the operative component of the da Vinci SP Surgical System. It supports the positioning of the surgical port and manipulation of the surgical instruments and endoscope.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

da Vinci SP Surgical System, Model SP1098

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Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

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

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device technological changes are limited to modified software. The subject device includes a new software feature called "Surgeon Cloud Accounts". The da Vinci SP Surgical System communicates with the network which includes servers, databases, and data storage solutions. The network architecture provides support for the Surgeon Cloud Accounts feature. Existing dedicated network processor which is allocated for all networking tasks to help provide security isolation from critical surgical system operation, is being extended to secure surgeon cloud accounts.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Verification and validation testing, consisting of software testing, cybersecurity testing, and clinical validation, on the subject device confirmed that no issues of safety or effectiveness and no additional unexpected risks were identified.

Human factors evaluation has been conducted to demonstrate safety and effectiveness of the subject device. The results of this evaluation concluded that the subject device is safe and effective for its intended use, by its intended users, and in its intended use environment.

Based on the intended use, indications for use, technological characteristics, and performance data, the subject da Vinci SP Surgical System is substantially equivalent to its predicate device.