December 15, 2025

Intuitive Surgical, Inc.
Mike Yramategui
Fellow Regulatory Engineer
1020 Kifer Road
Sunnyvale, California 94086

Re: K252675
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: November 13, 2025
Received: November 13, 2025

Dear Mike Yramategui:

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: 2025.12.15 08:46:28 -05'00'

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.	K252675

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 da Vinci 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 also indicated for use in nipple sparing mastectomy (NSM) procedures. 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 also indicated for use in nipple sparing mastectomy (NSM) procedures. 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)

510(k) Summary [21 CFR § 807.92(c)]

I. SUBMITTER INFORMATION

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

Contact: Mike Yramategui
Fellow Regulatory Engineer
Phone Number: 408-523-2145
Fax Number: 408-523-8907
Email: Mike.Yramategui@intusurg.com

Date Summary Prepared: August 21, 2025

II. SUBMITTER INFORMATION

Trade Name:	da Vinci SP® Surgical System, Model SP1098, da Vinci SP® Instruments, and Accessories
Common Name:	System, Surgical, Computer Controlled Instrument
Classification Name:	Endoscope and Accessories (21 CFR §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, Model SP1098,
da Vinci SP Instruments, and Accessories (K243714)

IV. DEVICE DESCRIPTION

The da Vinci SP Surgical System is designed to enable complex surgical procedures using a minimally invasive approach. The system consists of a Surgeon Console, a Vision Cart, and a Patient Cart and is used with an endoscope, instruments, and accessories.

The surgeon seated at the Surgeon Console controls all movement of the instruments and endoscope by using two hand controls and a set of foot pedals. The surgeon views the endoscopic 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 light source, video and image processing, and the networking hardware. The Vision Cart also has a touchscreen to view the endoscopic image and adjust system settings.

The Patient Cart is the operative component of the da Vinci SP Surgical System. Its primary function is to support the positioning of the surgical port and to manipulate the surgical instruments and endoscope. The Patient Cart is positioned beside the operating room table and contains an instrument arm that is positioned with respect to the target patient anatomy. The instrument arm contains four instrument drives that hold up to three surgical instruments and the endoscope. The bedside surgical assistant installs and removes the endoscope and instruments intra-operatively as needed.

This 510(k) is for a labeling modification only, to add “nipple sparing mastectomy (NSM) procedures” to the indications, and to add “nipple sparing mastectomy” as new representative, specific procedures in the Professional Instructions for Use. There have been no technical changes to the device.

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 da Vinci 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 also indicated for use in nipple sparing mastectomy (NSM) procedures.** 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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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 also indicated for use in nipple sparing mastectomy (NSM) procedures.** 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.

V. COMPARISON OF INTENDED USE, INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The da Vinci SP Surgical System, Model SP1098 and da Vinci SP Instruments and Accessories are unchanged from the predicate device in terms of intended use, design, performance, and technological characteristics. The labeling has been changed to add "nipple sparing mastectomy (NSM) procedures" to the indication statement and as new representative, specific procedure in the Professional Instructions for Use.

VI. PERFORMANCE DATA

The addition of nipple sparing mastectomy (NSM) surgical procedures to the SP1098 Indications does not change any of the safety or performance requirements that were previously verified and / or validated for the SP1098 regarding cleaning, sterilization, packaging, shelf life, biocompatibility, software, cybersecurity, electrosurgical performance, electromagnetic compatibility, electrical safety, mechanical and electrical performance, reliability, or human factors for use in urologic (K173906), transoral surgery (K182371), general thoracoscopic surgical procedures (K240502), colorectal surgical procedures (K242318), or transanal local excision (K243714).

Performance Testing - Bench

Design validation was performed to determine clinical suitability of the SP1098 for use in nipple sparing mastectomy and axillary lymph node dissection (ALND). The SP1098 system was tested in a simulated clinical laboratory setting and a female human cadaver was used for evaluation. A bilateral NSM and bilateral ALND were performed. The cadaver was positioned with their arm above the head for one breast and their arm along the side of the OR table for the other breast. The surgical approach is symmetrical and this patient positioning is the same for either breast. The NSM and ALND were able to be performed through a single incision on each of the breasts. The SP1098 system met all acceptance criteria for all test cases.

Performance Testing - Clinical

A prospective, multi-center randomized controlled trial (RCT) was conducted to evaluate performance of the da Vinci SP in nipple sparing mastectomy (NSM) procedures, and to provide a direct comparison between SP NSM to open NSM as the current standard of care. The RCT included NSM performed for early-stage cancer (therapeutic breasts) as well as prophylactic breasts if elected by the patient on the contralateral breast. There were 26 subjects (total of 46 breasts) in the SP arm and 27 subjects (total of 48 breasts) in the Open arm. All the NSM procedures were followed by an immediate one- or two-stage implant-based reconstruction procedure via an open approach. Overall safety was demonstrated by showing no differences in short term safety outcomes, and effectiveness was demonstrated by no conversions to an open approach and “no ink on tumor” in the SP cohort. The table below provides a summary of the key outcomes between SP NSM as the Subject Device and open NSM.

Comparison of key outcomes between SP NSM vs. Open NSM

	SP RCT	Open RCT
Number of Subjects	26	27
Therapeutic Breasts	27	27
Prophylactic Breasts	19	21
Total Breasts	46	48
Patient Characteristics		
Age (years) Mean (SD)	49.3 (9.19)	45.6 (11.45)
BMI Mean (SD)	21.7 (2.48)	22.9 (2.95)
Breast Ptosis n (%)		
Grade-0	8 (30.8%)	7 (25.9%)
Grade-1	13 (50.0%)	12 (44.4%)
Grade-2	5 (19.2%)	8 (29.6%)
Breast Cup Size n (%)		
A	5 (19.2%)	4 (14.8%)
B	17 (65.4%)	15 (55.6%)
C	4 (15.4%)	8 (29.6%)
Clinical T stage, n (%)		
DCIS/Tis	3 (11.1%)	7 (25.9%)
T0	0 (0.0%)	1 (3.7%)
T1	15 (55.6%)	13 (48.1%)
T2	9 (33.3%)	6 (22.2%)
Tumor Size (cm) Mean (SD)	1.8 (1.06)	1.6 (1.22)
History of Chemotherapy or other Neo-adjuvant Therapy n(%)	4 (15.4%)	7 (25.9%)
Clinical Outcomes		
Total Number of Breasts	**46**	**48**
NSM Procedure Time/per breast(minutes) Mean (SD)	128.3 (61.62)	85.4 (46.62)
Reconstruction Procedure Time/per breast (minutes) Mean (SD)	80.4 (41.12)	64.2 (31.89)
Conversion to Open, n (%)	0 (0%)	NA
SAE Rate[a] n (%)	1 (3.8%)	6 (22.2%)
Number of Subjects with SAE classified as Clavien-Dindo Grade III[b,c], n (%)	1 (3.8%)	6 (22.2%)
Number of Subjects with an UADE, n (%)	0 (0.0%)	0 (0.0%)
Device Related SAEs[d]	0	2
NAC related SAE	0	0
Skin-Flap Related SAE	0	0
NAC Preservation (42 days)	100%	93.5 %
Unplanned reoperations n (%)[c]	1 (3.8%)	6 (22.2%)
Unplanned readmission n (%)[e]	0	1 (3.7%)
Mortality	0	0
Number of Breasts with Positive Surgical Margin	4 (14.8%)	5 (18.5%)
Number of breasts with “ink on tumor”	0 (0%)	1 (3.7%)
Number of breasts with PSM due to DCIS ≤2mm	4 (14.8%)	4 (14.8%)

Notes

[a]All SAEs reported were resolved at data cutoff, except one SAE in the Open RCT cohort.

[b]There were no Grade IV or Grade V adverse events.

[c]All SAEs across both cohorts were classified as Clavien-Dindo Grade III, requiring unplanned reoperations.

[d]There were two (2) device-related SAEs in two (2) subjects in the Open RCT Cohort. Both SAE's were deemed to be related to NSM, the reconstruction procedure, and the devices used during open NSM.

[e]One (1) subject in the Open RCT Cohort had an unplanned readmission due to infection of the left breast implant received during one-stage reconstruction that required removal, washout, and IV antibiotics.

Acronyms:

DCIS: Ductal Carcinoma in Situ, NAC: Nipple-Areolar Complex, PSM: Positive Surgical Margin, SAE: Serious Adverse Event, UADE: Unanticipated Adverse Device Effect.

I. CONCLUSION

The da Vinci SP Surgical System has the same technological characteristics as it is unmodified from the predicate device, and there are no changes to the intended use for these labeling changes.

Bench testing demonstrates the ability of the da Vinci SP Surgical System to perform nipple sparing mastectomy (NSM) procedures. Clinical data from a prospective, randomized clinical trial demonstrates that da Vinci SP is comparable to open NSM, and do not raise different questions of safety or effectiveness.

Thus, these labeling changes to the da Vinci SP Surgical System are substantially equivalent to the cleared predicate device.