April 24, 2025

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

Re: K243714
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: March 26, 2025
Received: March 26, 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: 2025.04.24 11:41:08 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243714

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 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 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.

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: April 23, 2024

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 (K242318)

Reference Device: Applied Medical
GelPOINT Path Transanal Access Platform (K171701)

IV. DEVICE DESCRIPTION

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

The surgeon seated at the Surgeon Console controls all movement of the instruments and camera by using two hand controls and a set of foot pedals. The surgeon views the camera 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 camera light source, video and image processing, and the networking hardware. The Vision Cart also has a touchscreen to view the camera 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 camera. The Patient Cart is positioned at the operating room 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 camera. The patient-side assistant installs and removes the camera and instruments intra-operatively.

This 510(k) is for a labeling modification only, to add "transanal local excision (TALE)" as a new representative, specific procedure in the Professional Instructions for Use.

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 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.

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 "transanal local excision (TALE)" to the labeling as new representative, specific procedure in the Professional Instructions for Use.

VI. PERFORMANCE DATA

The addition of transanal local excision (TALE) to the labeling 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) or colorectal surgical procedures (K242318).

Bench Performance Testing

Design validation was performed in a male cadaver to confirm the clinical performance of the da Vinci SP Surgical System, including the SP Access Port Kit and SP Cannula with a third-party port under its intended use. Evaluation of the ability to provide robotic and laparoscopic instrument access to the rectum while remaining securely installed during use with either the SP Access Port Kit or compatible third-party port was confirmed. Assessment of instrument motion throughout the TALE procedure, and ability to reach targeted anatomy and complete the procedure was also confirmed. Two complete TALE procedures were performed, one with the

SP Access Port kit and another with a third-party port, and covers all issues of safe and effective use of the da Vinci SP Surgical System, with either the SP Access Port Kit or third-party port in the following representative procedure:

- Transanal local excision (TALE), also known as transanal local resection (TALR) or transanal minimally invasive surgery (TAMIS)

Design verification testing was performed to confirm that insufflation leakage between the SP Cannula when used with the compatible third-party port was within specification.

Published Clinical Data

Published clinical data comparing transanal local excision (TALE) using the da Vinci SP system to existing hand-held instruments performing the same procedure (referred to as TEM, TAMIS and TEO for handheld devices) were also provided. Peer-reviewed literature published between January 2018 and October 2024 on robotic-assisted TALE using the da Vinci SP system were identified by systematically searching the PubMed, Scopus and Embase databases. After systematic screening, 10 publications including one additional recent publication (submitted manuscript) reporting relevant clinical outcomes for TALE were identified for data review, and 4 of the 10 publications with high LOE (Level of Evidence 4 or better) were included for comparison. Publications for handheld devices performing TEM, TAMIS and TEO were similarly searched and screened, and after inclusion and exclusion criteria were applied, 42 studies for transanal local excisions/resections with Level of Evidence (LOE) 1-3 were identified and included for comparison. **Table 1** includes the ranges of average values or rates extracted for each clinical outcome for comparison between approaches and demonstrates similar ranges of outcomes between the surgical approaches listed and a listing of the publications is provided in the bibliography below.

VII. 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 or indications for use for these labeling changes.

Design validation testing provided demonstrates the ability of the da Vinci SP Surgical System to perform transanal local excision (TALE). A review of the published literature provides additional confirmation that outcomes of TALE with the da Vinci SP Surgical System are substantially equivalent to existing hand-held devices for performing TALE 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.

Table 1: SP TALE and Hand-held Devices Literature Comparison

	SP Transanal Local Excision (TALE)[a]		Transanal Procedures with Hand-held Devices (TEM/TEO/TAMIS)[b]
	Full and Partial-thickness Resection[c]	**Partial-thickness Resection Only[d]**	
# Included Publications (Total Patient Count)	2 publications[1,3], 43 patients	2 publications[2,4], 38 patients	42 publications[1-42], ~21121 patients
Study Type	Prospective, Retrospective	Prospective, Retrospective	Prospective, Retrospective, Meta-analysis
Level of Evidence (LOE)	4	4	1-3
Port/Other instruments used	Da Vinci SP system and SP instruments. Access device: GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA) (n=26), or SP Access Port (n=17)	Da Vinci SP system and SP instruments. Access device: GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA) (n=38)	TEM equipment (Wolf, Knittlingen, Germany); or TEO platform by Karl Storz (Tüttlingen, Germany); or regular laparoscopic devices with access device for TAMIS. Access device: GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA) or SILS Port (Covidien, Mansfield, MA)
Depth of Dissection	Full-thickness excision in **70.6%**[3] **– 84.6%**[1] of patients, partial-thickness resection in **15.4%**[1] **–29.4%**[3] of patients	**100%**[2,4] partial-thickness resection	Full-thickness excision in **0%**[21] **– 100%**[1,4,13,18,27] of all patients, or **100%**[20] in the TEM/TEO/TAMIS subgroup
Patient and Lesion Characteristics			
Average Age	**63.9**[3]	**60.5**[4] **– 68**[2]	**43**[38] **– 76**[15]
Sex (Male)	**50%**[1] **– 76%**[3]	**67.8%**[4] **– 86%**[2]	**23%**[39] **– 82.9%**[1]
Average BMI	(range) **21.0**[1] **– 38.1**[1]	**28.2**[4] **– 29.38**[2]	**22.88**[36] **– 28.2**[1]
ASA Class	I: **3.8%**[1] II: **69.2%**[1] III: **26.9%**[1]	I: **20%**[2] II: **50%**[2] III: **30%**[2] II-III: **82%**[4]	I: **0.8%**[34] **– 45%**[5] II: **45%**[34] **– 85.2%**[20] III: **0%**[8,20] **– 42.4%**[34] IV: **3.85%**[26] **– 12%**[34] III-IV: **15.8%**[2] **– 31%**[22]
Lesion Type	**29%**[3] **– 38.5%**[1] malignant (rectal adenocarcinoma), **61.5%**[1] **– 71%**[3] benign preop indication; **29%**[3] malignant at final pathology	**100%**[2,4] preop benign rectal neoplasms (non-malignant polyps); **20%**[2] **– 21.4%**[4] malignant (adenocarcinoma) at final pathology	Benign, Malignant
Tumor Staging	T0 to T4 at presentation[1]; T1 to T3 at final pathology[1,3]	Benign at preop[2,4]; T1[2] to unspecified-stage adenocarcinoma[4] at final pathology	Tis, T1, T2, T3
Average Lesion/Adenoma/Tumor Size (cm)	**2.9**[1]	**3.8**[4] **– 4.23**[2]	**0.6**[14] **– 6.7**[7]
Average Distance from Anal Verge (cm)	**4.8**[1] **– 5**[3]	**7.3**[2] **– 9**[4]	**3.3**[20] **– 17**[34]

	SP Transanal Local Excision (TALE)[a]		Transanal Procedures with Hand-held Devices (TEM/TEO/TAMIS)[b]
	Full and Partial-thickness Resection[c]	Partial-thickness Resection Only[d]	
Key Outcomes			
Average Operative Time (minutes)	**32.1**[3] **– 198.8**[1]	**87.5**[4] **– 91.3**[2]	**38**[29] **– 192**[20]
Average EBL (mL)	**5**[3] **– 24.21**[1]	NR	**5.00**[4] **– 143**[23]
Transfusion Rate (%)	**0%**[1,3]	**0%**[4]	**4.3%**[16] **– 5.3%**[16]
Conversion to Open Surgery (%)	**0%**[1,3]	**0%**[4]	**0%**[4,21] **– 5.13%**[28]
Negative Surgical Margin (%)	**100%**[1,3]	**100%**[2]	**66%**[5] **– 100%**[4,36]
Intraoperative Complication Rate (%)	**0%**[1,3]	**0%**[2,4]	**0%**[7,27] **– 1.8%**[31]
30-day Postoperative Complication Rate (%)	**11.8%**[3] **– 15.4%**[1]	**7.1%**[4] **– 20%**[2]	**5%**[18] **– 40%**[39]
Major (C-D grade ≥ III) Complication Rate (%)	NR	NR	**0%**[21,38] **– 11%**[39]
Average Length of Hospital Stay (days)	**0**[3] **– 1**[1]	**0**[2,4]	**0.4**[22] **– 6.0**[20]
Re-admission/Re-operation rate (%)	Re-admission: **11.8%**[3] Re-operation: **0%**[1,3]	Re-admission: **10%**[2]	**0%**[36] **– 9.1%**[2]
Overall Mortality Rate (%)	**0%**[1,3]	**0%**[2,4]	**0%**[19,28,29,31,39,41] **– 7.1%**[12]
Postoperative and Oncological Outcomes			
Delayed or Long-term Postoperative Complication Rate (more than 30 days after surgery) (%)	**0%**[1]	NR	**25.9%**[20]
Bleeding	**0%**[1] **– 5.9%**[3]	**3.6%**[4] **– 10%**[2]	**0%**[4,36] **– 17%**[5,39]
Perforation	NR	NR	**0%**[6,14,19,36,38] **– 5.5%**[32]
Strictures/Stenosis	NR	NR	**0%**[4,23,41] **– 4.5%**[5]
Wound Dehiscence	**0%**[3] **– 11.5%**[1]	**0%**[2,4]	**0%**[5] **– 17.6%**[31]
Other Complications reported >1%	Pelvic abscess: **3.8%**[1] Pain: **5.9%**[3]	Urinary retention: **3.6%**[4] – **10%**[2]	Post-polypectomy syndrome: **22.2%**[6] Infection/abscess: **1.8%**[28] **– 20%**[19] Illeus/gastroparesis: **1.1%**[5] Myocardial infarction: **1.1%**[5] Respiratory failure: **1.1%**[5] Urinary tract infection: **3.4%**[5] **– 4.3%**[16] Urinary retention: **2.6%**[28] **– 13.6%**[36]

	SP Transanal Local Excision (TALE)[a]		Transanal Procedures with Hand-held Devices (TEM/TEO/TAMIS)[b]
	Full and Partial-thickness Resection[c]	Partial-thickness Resection Only[d]	
			High body temperature: **8%**[26] Pain: **1%**[26] **– 26.4%**[23] Delayed healing: **2.4%**[42] Crepitation on upper extremity: **4.3%**[16] Pneumonia: **2%**[19] **– 2.1%**[23] Other: **2.3%**[5]
Average Follow-up time (month)	**5.9**[1]	**6**[2]	**1**[28,29] **– 129.6**[26]
Recurrence rate (%)	Local recurrence: **0%**[1]	Local recurrence: **0%**[2]	Local recurrence: **0%**[14,38] **– 30%**[15] Distant metastasis: **0.7%**[27] **– 33%**[15]
Peritoneal Entry-related Outcomes			
Peritoneal entry	In one paper[1], the peritoneal cavity was entered in **19%** patients (all closed uneventfully with the SP robot; these were all in full-thickness excision cases)[1] In one other paper[3], no mention of peritoneal entry[3]	No mention of peritoneal entry[2,4]	**0%**[8] – **23.7%**[34]

[a] Four publications with LOE 4 or better from 01 Jan 2018 – 22 Oct 2024 including one paper in peer review on SP TALE procedures with the SP Access Port or GelPOINT Path Transanal Access Platform were included as SP TALE Literature.
[b] Publications from 01 Jan 2018 – 16 Dec 2023 on TEM/TEO/TAMIS with LOE 1-3 and relevant results were included for this subgroup.
[c] Among the four papers in SP TALE literature, two papers with mixed full-thickness excision and partial-thickness resections were included for this subgroup.
[d] Among the four papers in SP TALE literature, two papers with all partial-thickness resections were included for this subgroup.
ASA: American Society of Anesthesiologists; BMI: Body mass index; C-D: Clavien-Dindo; EBL: Estimated Blood Loss; LOE: Level of Evidence; NR: Not Reported; TAMIS: Transanal minimally invasive surgery; TEM: Transanal endoscopic microsurgery; TEO: transanal endoscopic operation.
Data represent the smallest ─ largest Mean/Median (for numerical variables) or Rate (for categorical variables) from all publications that reported relevant results for each data category.

Bibliography for SP Transanal Literature (n=4)

1. Marks JH, Kunkel E, Salem JF, Martin CT, Anderson B, Agarwal S. First Clinical Experience With Single-Port Robotic Transanal Minimally Invasive Surgery: Phase II Trial of the Initial 26 Cases. Dis Colon Rectum. 2021;64(8):1003-13.
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4. Bai X, Zhou W, Li Y, Lin G. Transanal endoscopic microsurgery with alternative neoadjuvant imatinib for localized rectal gastrointestinal stromal tumor: a single center experience with long-term surveillance. Surgical Endoscopy. 2021;35(7):3607-17.

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