April 5, 2023

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

Re: K230033
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: January 3, 2023
Received: January 5, 2023

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 (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 and the limitations described below. 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 located 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.

The OHT4: Office of Surgical and Infection Control Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the device's labeling:

The safety and effectiveness of this device for use in the performance of general laparoscopic surgery procedures have not been established. This device is only intended to be used for single port urological procedures and for transoral otolaryngology surgical procedures in the oropharynx for benign tumors and malignant tumors classified as T1 and T2 with the da Vinci EndoWrist SP Instruments and the da Vinci SP Surgical System (SP1098).

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

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

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

David Krause -S

for Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230033

Device Name

da Vinci SP Surgical System, Model 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 EndoWrist SP Instruments during urologic 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.

EndoWrist SP Instruments:
Intuitive Surgical EndoWrist 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 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 4, 2023

II. SUBMITTER INFORMATION

Trade Name:	da Vinci SP® Surgical System, Model SP1098, EndoWrist 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, EndoWrist SP Instruments, and Accessories (K202571)

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 “simple prostatectomy” as a new representative, specific procedure in the Professional Instructions for Use. Simple prostatectomy is a “covered” procedure under radical prostatectomy as an “umbrella” procedure. This 510(k) also includes the addition of performance data (cadaver) for “transvesical prostatectomy” as validated approach for prostatectomy in the Performance Data section of the User Manual.

V. 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 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.

EndoWrist SP Instruments:
Intuitive Surgical EndoWrist 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 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

VI. COMPARISON OF INTENDED USE, INDICATIONS FOR USE AND TECHNOLOGAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The da Vinci SP Surgical System, Model SP1098 and EndoWrist 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 "simple prostatectomy" as a new representative, specific procedure in the Professional Instructions for Use as a "covered" procedure under the existing clearance for radical prostatectomy as an "umbrella" procedure, and benign and radical transvesical prostatectomy as umbrella procedures.

VII. PERFORMANCE DATA

This 510(k) is for a labeling modification only and there are no technological changes made to the subject device. Thus, previous bench testing related to electromagnetic compatibility, electrical safety, software, biocompatibility, sterilization, and shelf life were not impacted by this change.

Simple prostatectomy was added as a new representative, specific "covered" procedure in the Professional Instructions for Use under the cleared "umbrella" radical prostatectomy procedure. No performance testing was necessary to add simple prostatectomy as a representative, specific procedure.

Design validation testing was performed in a male cadaver to confirm the ability of the SP1098 for performing a transvesical prostatectomy. Evaluation of the ability to provide robotic and laparoscopic instrument access to the deep pelvis via an incision in the urinary bladder was confirmed and an assessment of instrument motion throughout the prostatectomy procedure was performed. Evaluation of SP Access Port Kit robustness as well as the ability of the SP Access Port Kit to provide adequate retraction for SP instrument access while remaining securely installed during use was also evaluated.

Real-World Evidence (RWE) supporting the substantial equivalence of transvesical prostatectomy to previously cleared extraperitoneal prostatectomy (EPRP) and transabdominal prostatectomy (TARP) was also provided. Peer-reviewed literature published between Jan 01, 2018 and January 7, 2023 on robotic-assisted surgery using the SP1098 were identified by systematically searching the Scopus, Embase, and PubMed databases. After systematic literature screening, 11 primary publications reporting relevant clinical outcomes for transvesical simple/radical prostatectomy performed using the da Vinci SP Surgical System were included for comparison. Publications for extraperitoneal and transperitoneal approaches to prostatectomy using the SP1098 were similarly screened, and all primary publications reporting relevant clinical outcomes with 50 or more patients in at least one study arm were included, resulting in 10 publications reporting EPRP data and 7 publications reporting TARP data. Table 1 includes the ranges of raw values extracted for each clinical outcome for comparison between approaches. The data in Table 1 demonstrate similar ranges of outcomes between the surgical approaches listed. Table 2 provides a listing of the publications.

VIII. CONCLUSION

The da Vinci SP Surgical System is unmodified from the predicate device, and there are no changes to the intended use or indications for use for these labeling changes. The addition of simple prostatectomy as a representative procedure does not represent a change or modification that requires clinical data to evaluate safety or effectiveness of the device. It does not introduce any different issues of safety or effectiveness as compared to the urological procedures previously cleared for the SP1098 system.

Design validation testing provided demonstrates the ability of the da Vinci SP Surgical System to perform transvesical prostatectomy. A review of the published literature (RWE) provides additional confirmation that a transvesical approach (TVSP / TVRP) is substantially equivalent to the cleared transabdominal approach (TARP) and extraperitoneal (EPRP) approaches for performing radical prostatectomy, 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: Literature Summary Table: da Vinci SP Transvesical vs. Extraperitoneal and Transabdominal Prostatectomy*

Outcome	Transvesical Prostatectomy (TVP)[a]		Extraperitoneal Radical Prostatectomy (EPRP)[b] (K202571)	Transabdominal Radical Prostatectomy (TARP)[b] (K173906)
	Simple (TVSP) for benign indications	Radical (TVRP) for prostate cancer		
# Included Publications (Total Patient Count)	8 publications[1-8], ~247 patients	3 publications[9-11], ~181 patients	10 publications[10,12-20], ~1,259 patients	7 publications[16,20-25], ~649 patients
Operative Time (Avg)	153[4] – 232.4[3] min	199[9] – 212[11] min	147[15] – 203.2[13] min	114[25,24] – 248.2[16] min
EBL (Avg)	100[1,2,4,8] – 227.1[3] mL	100[10] – 135[9] mL	50[15] – 197.2[13] mL	50[23-25] – 200[21] mL
Conversion Rate	0%[4,7]	0%[9]	0%[12,13,16,17,19]	0%[16,21]
Intraoperative Complication Rate	0%[2,4,5,7] – 2.4%[6]	0%[9,11]	0%[12,13,17,19] – 2.0%[15]	0%[23-25] – 2.7%[20]
30-Day Postoperative Complication Rate	0%[5] – 12.5%[4,c]	5.0%[9,d] – 12.8%[10]	3.8%[17] – 18.3%[19]	0%[23,24] – 15.2%[16]
Major (C-D grade ≥ III) Complication Rate	0%[4,6,8] – 7.14%[3,e]	0%[9] – 2.6%[10]	0%[15] – 11.7%[19]	0%[23,24] – 6.5%[16]
Length of Stay	<24 hrs[2,4,6-8] – 2.5 days[3]	<24 hrs[9-11]	<24 hrs[10,12-14,16,19,20] – 2 days[17]	<24 hrs[20,22,23] – 7 days[21]
30-Day Readmission Rate	1.0%[8]	5.0%[9,d] – 5.1%[10]	2.0%[15] – 8.6%[14]	0%[23-25] – 6.4%[22]
Urinary Retention Rate	0%[2,4] – 4.4%[8]	5.1%[10]	0.6%[17] – 2.6%[10]	1.3%[20]
90-Day/3-Month Continence Rate	90%[5,f] – 100%[2]	96.6%[10] – 97%[11]	38.4%[15] – 85%[13]	62.5%[16] – 78%[23]
Urinary Catheterization Time (Avg)	1.9[5] – 10.5[3] days	3[10] – 4[9,11] days	7 days[10,14,15,20]	5 days[20,23,24,25]
Positive Surgical Margins	NA	14.5%[11] – 15.4%[10]	17.3%[15] – 29%[17]	14%[23] – 41.3%[16,g]
Overall Mortality	0 (0%) at 30 days[3]	NR	NR	NR

[a]All primary publications from 01 Jan 2018 – 07 Jan 2023 included
[b]Primary publications from 01 Jan 2018 – 07 Jan 2023 with n ≥ 50 patients in at least one study arm included
[c]Low sample size (1/8 patients). Next highest postoperative complication rate reported for TVSP: 11% (10/91 patients)[8]
[d]Low sample size (1/20 patients) representing a single minor (C-D grade I) complication
[e]No other TVSP publication reported major (C-D grade ≥ III) complications
[f]Low sample size (9/10 patients). Next lowest continence rate reported for TVSP: 97% (41/42 patients)[6]
[g]16/19 had high risk features: n=15 patients with T3abN0-1, n=1 patient with T2N0 with GrGp4-5
Complication /Adverse Event; C-D: Clavien-Dindo; EBL: Estimated Blood Loss; EPRP: Extraperitoneal Radical Prostatectomy; IQR: Interquartile Range; NA: Not Applicable; NR: Not Reported; TARP: Transabdominal Radical Prostatectomy; TVRP: Transvesical Radical Prostatectomy; TVSP: Transvesical Simple Prostatectomy
* Literature summary table provides data as extracted from publications and were not statistically analyzed

Table 2: List of Publications Reviewed

Author(s)	Title
1. Ganesan V, Steinberg RL, Garbens A, et al.	Single-port robotic-assisted simple prostatectomy is associated with decreased post-operative narcotic use in a propensity score matched analysis. *Journal of Robotic Surgery.* 2021.
2. Kaouk J, Sawczyn G, Wilson C, et al.	Single-Port Percutaneous Transvesical Simple Prostatectomy Using the SP® Robotic System: Initial Clinical Experience. *Urology.* 2020.
3. Khalil MI, Chase A, Joseph JV, Ghazi A.	Standard Multi-Port versus Single-Port Robot-Assisted Simple Prostatectomy: A Single Center Initial Experience. *Journal of endourology.* 2022.
4. Sawczyn G, Aminsharifi A, Garisto J, Valero R, Kaouk J.	Single-port transvesical robotic simple prostatectomy using the novel SP surgical system: Technical aspects. *Urology Video Journal.* 2020;5.
5. Steinberg RL, Passoni N, Garbens A, Johnson BA, Gahan JC.	Initial experience with extraperitoneal robotic-assisted simple prostatectomy using the da Vinci SP surgical system. *Journal of robotic surgery.* 2019.
6. Zeinab AM, Kaviani A, Ferguson E, et al.	Single-port transvesical versus open simple prostatectomy: a perioperative comparative study. *Prostate Cancer Prostatic Dis.* 2022.
7. Zeinab AM, Kaviani A, Ferguson E, Beksac T, Eltemamy M, Kaouk J.	A Transition Towards A Faster Recovery in Single-Port Transvesical Simple Prostatectomy. *J Endourol.* 2022.
8. Zeinab MA, Beksac AT, Corse T, et al.	The Multi-Institutional Experience in Single-Port Robotic Transvesical Simple Prostatectomy for BPH Management. *J Urol.* 2022:101097ju0000000000002692.
9. Kaouk J, Beksac AT, Zeinab MA, Duncan A, Schwen ZR, Eltemamy M.	Single Port Transvesical Robotic Radical Prostatectomy: Initial Clinical Experience and Description of Technique. *Urology.* 2021.
10. Zeinab AM, Beksac AT, Ferguson E, Kaviani A, Kaouk J.	Transvesical versus extraperitoneal single-port robotic radical prostatectomy: a matched-pair analysis. *World J Urol.* 2022;40(8):2001-2008.
11. Zeinab AM, Kaviani A, Ferguson E, Beksac AT, Kaouk J.	Single-port transvesical robotic radical prostatectomy: Description of technique. *Urology Video Journal.* 2022;15.
12. Aminsharifi A, Hemal S, Aram P, Abou Zeinab M, Beksac T, Kaouk J.	The performance and optimum cutoff value for pelvic cavity index as a predictor of early continence after extraperitoneal single-port robotic radical prostatectomy: Role of pelvic anatomical characteristics. *J Endourol.* 2022.
13. Aminsharifi A, Wilson CA, Sawczyn G, Kim S, Lenfant L, Kaouk J.	Predictors associated with a prolonged hospital stay after single-port extraperitoneal robotic radical prostatectomy: A comparative analysis of outpatient versus inpatient care. *J Endourol.* 2020.
14. Beksac AT, Zeinab MA, Ferguson E, Kaviani A, Kaouk J.	Single-Port Extraperitoneal Robot Assisted Radical Prostatectomy – Description of Technique. *Urology Video Journal.* 2022;15.
15. Harrison R, Stifelman M, Billah M, et al.	Propensity-Score Matched Analysis Between Extraperitoneal Single Port and Intraperitoneal Multiport Radical Prostatectomy: A Single-Institutional Experience. *Urology.* 2022.
16. Kaouk J, Aminsharifi A, Wilson CA, et al.	Extraperitoneal versus Transabdominal Single-Port Robotic Radical Prostatectomy: A Comparative Analysis of Perioperative Outcomes. *The Journal of urology.* 2019:101097JU0000000000000700.
17. Kim J, Kaldany A, Lichtbroun B, et al.	Single Port Robotic Radical Prostatectomy: Short-term Outcomes and Learning Curve. *J Endourol.* 2022.

Author(s)	Title
18. Lenfant L, Corrigan D, Beksac AT, Schwen Z, Kaouk J.	Learning curve analysis of single-port robot-assisted extraperitoneal prostatectomy using the cumulative sum (CUSUM) method. *BJU Int.* 2021.
19. Wilson CA, Aminsharifi A, Sawczyn G, et al.	Outpatient Extraperitoneal Single-port Robotic Radical Prostatectomy. *Urology.* 2020.
20. Zeinab AM, Beksac AT, Ferguson E, et al.	Single-port Extraperitoneal and Transabdominal Radical Prostatectomy: A Multi-Institutional Propensity-Score Matched Study. *Urology.* 2022.
21. Kim KH, Ahn HK, Kim M, Yoon H.	Technique and perioperative outcomes of single-port robotic surgery using the da Vinci SP platform in urology. *Asian J Surg.* 2022.
22. Lenfant L, Sawczyn G, Kim S, Aminsharifi A, Kaouk J.	Single-institution Cost Comparison: Single-port Versus Multiport Robotic Prostatectomy. *European Urology Focus.* 2020.
23. Moschovas CM, Bhat KRS, Onol F, Rogers T, Patel V.	Early outcomes of Single Port Robotic Radical Prostatectomy.Lessons Learned from The learning curve experience. *BJU Int.* 2020.
24. Moschovas CM, Bhat KRS, Sandri M, et al.	Comparing the Approach to Radical Prostatectomy Using the Multiport da Vinci Xi and da Vinci SP Robots: A Propensity Score Analysis of Perioperative Outcomes. *Eur Urol.* 2020.
25. Moschovas CM, Kind S, Bhat S, et al.	Implementing the da Vinci SP Without Increasing Positive Surgical Margins: Experience and Pathologic Outcomes of a Prostate Cancer Referral Center. *Journal of Endourology.* 2022;36(4):493-498.