8 July 2024

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

Re: K240502
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 3, 2024
Received: June 3, 2024

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 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 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.

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 and general thoracoscopic surgical 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.

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.

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,

Barton Sachs -S
2024.07.08 17:08:09 -04'00'

Barton L. Sachs, M.D., MBA, F.A.C.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

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)*

K240502

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 EndoWrist SP Instruments during urologic 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.

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 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: July 1, 2024

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 (K231798)

Reference Device: da Vinci Xi Surgical System, Model IS4000, EndoWrist Instruments, and Accessories (K153276)

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 "general thoracoscopic surgical procedures" to the indications, and to add "lobectomy, segmentectomy, wedge resection, segmentectomy, lymphadenectomy, thymectomy, and mediastinal mass resection" as new representative, specific procedures 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 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.

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 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

V. 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 "general thoracoscopic surgical procedures" to the indication statement and to add "lobectomy, segmentectomy, wedge resection, segmentectomy, lymphadenectomy, thymectomy, and mediastinal mass resection" as new representative, specific procedures in the Professional Instructions for Use.

VI. PERFORMANCE DATA

The addition of general thoracoscopic 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) and transoral surgery (K182371).

Cadaver and Animal Performance Testing

Comparative animal and cadaver testing was conducted to demonstrate the equivalence of the SP1098 System to the multiport da Vinci Xi system, Model IS4000 for performing thoracoscopic surgical procedures. Cadavers were used to demonstrate device performance for anatomical access and reach. Live animals were used to assess safety and performance in cases where live tissue model was appropriate. These models replicate factors experienced during normal clinical use, including operating on perfused organs, normal tissue manipulation, and ensuring that appropriate hemostasis is achieved and maintained.

Three (3) independent practicing surgeons participated in a pre-clinical study using the SP1098 system to perform a set of general thoracoscopic surgical procedures. Each surgeon performed five (5) procedures in a cadaver model and one (1) procedure in a porcine model, for a total of 18 surgical procedures performed. Success criteria for each procedure are listed below (Table 1). In addition, surgeons completed questionnaires that evaluated their ability to perform surgical tasks of the SP1098 and the multiport system, IS4000, which is cleared for use in general thoracoscopic surgical procedures (K153276) and serves as a reference device for this 510(k).

Table 1

Surgical Procedure	Subject	Procedure Completion Acceptance Criteria
Right Upper Lobectomy with Lymphadenectomy	Cadaver	• Complete right upper lobe hilar dissection • Sufficient lymph node dissection • Exposure of vasculature, airway, and fissure for division complete and deemed surgically acceptable upon visual inspection • Suture closure of proximal bronchial stump complete and deemed surgically acceptable upon visual inspection • Critical anatomy identified
Right Lower Lobectomy with Lymphadenectomy	Cadaver	• Complete right lower lobe hilar dissection • Sufficient lymph node dissection • Exposure of vasculature, airway, and fissure for division complete and deemed surgically acceptable upon visual inspection • Critical anatomy identified
Left Upper Lobectomy with Lymphadenectomy	Cadaver	• Complete left upper lobe hilar dissection • Sufficient lymph node dissection • Exposure of vasculature, airway, and fissure for division complete and deemed surgically acceptable upon visual inspection • Critical anatomy identified
Left Lower Lobectomy with Lymphadenectomy	Cadaver	• Complete left lower lobe hilar dissection • Sufficient lymph node dissection • Exposure of vasculature, airway, and fissure for division complete and deemed surgically acceptable upon visual inspection • Critical anatomy identified
Thymectomy	Cadaver	• Sufficient mobilization of thymic tissue • Sufficient lateral dissection boundaries reached • Critical anatomy identified • Appropriate vessel ligation
Right Upper Lobectomy	Porcine	• Complete right upper lobe hilar dissection • Sufficient lymph node dissection • Exposure of vasculature, airway, and fissure for division complete and deemed surgically acceptable upon visual inspection • Suture closure of proximal bronchial stump complete and deemed surgically acceptable upon visual inspection • Hemostasis maintained

Clinical Study

A prospective, multicenter, single-arm, clinical study was conducted to confirm the pre-clinical safety and performance of SP1098 da Vinci Surgical System, Instruments, and Accessories in general thoracoscopic surgical procedures. This study also confirms that use of the SP1098 system in thoracoscopic surgical procedures does not raise different questions of safety or effectiveness. The study included 32 subjects at six (6) institutions in the United States and 13 thymectomy procedures and 19 lobectomy procedures were performed.

Safety was demonstrated by the incidence of intra-operative and post-operative adverse events reported through the 30-day follow-up. Performance was demonstrated by the rate of conversion from da Vinci SP surgery to an open, video-assisted thoracoscopic surgery (VATS), or a multi-port robotic (da Vinci Si/X/Xi) surgery. Results show that the device-related adverse event rate was 0% and there were no conversions. The study met its safety and performance endpoints.

Thymectomy Results

Thirteen (13) subjects were enrolled in the study for thymectomy for benign (N=6) and malignant conditions (N=7). Forty-six percent (46.2%) of thymectomy subjects enrolled in the study had at least one comorbidity, with hypertension being the most prevalent (83.3%). In addition, 33.3% of subjects had a prior history of cancer, and 16.7% had COPD.

All thymectomy procedures in the study were completed using a da Vinci SP Surgical System without conversion to open, VATS, or multiport robotic-assisted surgery, therefore, the conversion rate is 0% in the study for in the thymectomy cohort.

There were no intraoperative adverse events and no unanticipated device-related adverse effects (UADE) and no serious adverse events (SAE) reported. A total of four (4) subjects experienced 5 AEs with all of the AEs classified as minor (Clavien-Dindo Grade I and II) and no adverse event was classified as “Major” (Clavien-Dindo Grade III or higher). None (0) of the adverse events were deemed to be device related. **Table 2** summarizes the study results and **Table 3** lists the adverse events reported in the lobectomy cohort.

Table 2 summarizes the study data and **Table 3** provides a list of the adverse events reported in the thymectomy cohort.

Table 2. Results Summary (Thymectomy)

Clinical Study Parameter	Study Data K240502
Number of Subjects, n	13
Operative time (minutes), mean ± SD	193.3 ± 56.51
Estimated blood loss (mL), mean ± SD	11.9 ± 12.66
Blood transfusion rate, %	0
Conversion rate, %	0
Device-related adverse event rate, %	0
Intraoperative adverse event rate, %	0
Subjects with major AE (Clavien-Dindo Grade III/IV/V, n (%)	0
Subjects with minor AE (Clavien-Dindo Grade I/II), n (%)	4 (30.8%)
Length of hospital stay (days), mean ± SD	1.6 ±0.51
Rate of positive surgical margin, %, n= 7	0
Readmission rate, %	0
Reoperation rate, %	0
Mortality rate%	0

Table 3. Postoperative Adverse Events (Thymectomy)

Type	Total study N= 13
Subjects experiencing AEs	**4**
Total Number of AEs	**5**
Minor (Clavien-Dindo Grade I/II)	
Corneal abrasion	1
Delayed phrenic nerve, elevated left hemidiaphragm	1
Fatigue	1
Neuropathy	1
Pleural effusion	1

Lobectomy Results

Nineteen (19) subjects were enrolled in the study for lobectomy. Of these 19 subjects, 18 (94.7%) were malignant indications and 1 (5.3%) was for a benign indication. Seventy-four percent (73.7%) of lobectomy subjects had at least one comorbidity, with hypertension being the most prevalent comorbidity within the population of subjects (57.1%). In addition, 35.7% of the subjects had a prior history of cancer, 35.7% had COPD, 28.6% had diabetes, and 7.1% had cardiopulmonary disease and 7.1% had a history of cerebrovascular accidents.

All lobectomy procedures in the study were completed using a da Vinci SP Surgical System without conversion to open, VATS, or multiport robotic-assisted surgery, therefore, the conversion rate is 0% in the study for in the lobectomy cohort.

There were no intraoperative adverse events and no unanticipated device-related adverse effects (UADE) . Nine (9) subjects experienced at least one adverse event of which 4 subjects experienced Serious Adverse Events (SAEs), classified as "major" (Clavien Dindo Grade IIIa or higher). None (0) of the adverse events were deemed to be device related. **Table 4** summarizes the study results and **Table 5** lists the adverse events reported in the lobectomy cohort.

Table 4. Results Summary (Lobectomy)

Clinical Study Parameter	Study Data K240502
Number of Subjects, n	19
Operative time (min), mean ± SD	229.6 ± 64.14
Estimated blood loss (mL), mean ± SD	47.9 ± 47.41
Transfusion rate, %	0
Conversion to open rate, %	0
Device-related adverse event rate, %	0
Intraoperative adverse event, %	0
Subjects with major adverse events, AE (Clavien-Dindo Grade III/IV/V), n (%)	3 (15.8%)
Subjects with Minor adverse events, AE (Clavien-Dindo Grade I/II), n (%)	6 (31.6%)
Length of hospital stay (days), mean ± SD	3.8 ± 1.60
Rate of positive surgical margins, n (%)	0
Readmission rate, n (%)*	1 (5.3%)
Reoperation rate%	0
Mortality rate, %	0

* 1 subject had re-admission related to the AE

Table 5. Postoperative Adverse Events (Lobectomy)

Type	Total study N=19
Subjects experiencing AEs	**9**
Total number of AEs	**13**
Minor (Clavien-Dindo Grade I/II)	
Air leakage (extended chest tube duration)	1
Constipation	1
Exacerbation of pre-existing COPD	1
Fatigue	1
Hypoglycemia	1
Neuropathy	1
Pain/dyspnea associated with chest tube	1
Pneumothorax	1
Urinary retention	1
Major (Clavien-Dindo Grade III/IV)	
Acute Respiratory Failure	1
Air leakage (new chest tube or bronchial valve placed)	2
Atelectasis	1

Comparison of da Vinci SP Study Results to Literature on Multiport Robotic-assisted Thoracic Surgery

Results of this study of da Vinci SP were compared to recently published clinical literature between 2010 and 2022 on multiport robotic systems for thymectomy and lobectomy procedures. The multiport robotic system, IS4000, serves as a reference device for this comparison. Systematic literature searches were done for thymectomy, and lobectomy published literature in this time period, were conducted according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) methods. **Table 6** summarizes the comparison in thymectomies. **Table 7** summarizes the comparison in lobectomies. Each parameter from the literature is shown based on the pooled sample size from multiple publications and 95% confidence interval based on estimated weighted average and weighted standard deviation from multiple publications. **Table 8** provides a bibliography of the literature on multiport articles used for the comparison.

Comparison of the results from the da Vinci SP Surgical System to the published literature demonstrate that the 95% confidence intervals for all 12 clinical parameters in the SP study overlap the 95% CIs calculated from the published clinical literature on da Vinci Multiport systems for both thymectomy and lobectomy. This comparison demonstrates that the da Vinci SP Surgical System is as safe and effective as the predicate device and does not raise different questions of safety or effectiveness.

Table 6. da Vinci SP Thymectomy versus da Vinci Multiport Literature Comparison

Clinical Study Parameter	Study Data K240502	da Vinci Multi-port Literature
Operative time		
Sample Size	N = 13	N = 919
Mean +- SE	193.3 +- 15.67	133.1 +- 9.05
95% CI	[159.16, 227.46]	[114.16, 152.03]
Length of stay		
Sample Size	N = 13	N = 1897
Mean +- SE	1.6 +- 0.14	3.6 +- 0.28
95% CI	[1.31, 1.92]	[3.02, 4.17]
Estimated blood loss		
Sample Size	N = 13	N = 520
Mean +- SE	11.9 +- 3.51	63.95 +- 7.84
95% CI	[4.24, 19.53]	[46.69, 81.21]
Intra-operative adverse event		
Sample Size	N = 13	N = 73
Proportion	0.0%	4.1%
95% CI	[0%, 24.71%]	[0.58%, 7.58%]
Major adverse event rate (Clavien-Dindo III and IV)		
Sample Size	N = 13	N = 185

Clinical Study Parameter	Study Data K240502	da Vinci Multi-port Literature
Proportion	0.0%	1.6%
95% CI	[0%, 24.71%]	[0%, 4.75%]
Minor adverse event rate (Clavien/Dindo I and II)		
Sample Size	N = 13	N = 144
Proportion	30.8%	4.2%
95% CI	[9.09%, 61.43%]	[0%, 18.84%]
Transfusion rate		
Sample Size	N = 13	N = 126
Proportion	0%	0%
95% CI	[0%, 24.71%]	NA
Conversion rate		
Sample Size	N = 13	N = 1322
Proportion	0.00%	3.4%
95% CI	[0%, 24.71%]	[2.03%, 4.72%]
Mortality rate		
Sample Size	N = 13	N = 1778
Proportion	0.00%	0.3%
95% CI	[0%, 24.71%]	[0.04%, 0.51%]
Readmission rate		
Sample Size	N = 13	N = 576
Proportion	0.00%	3.8%
95% CI	[0%, 24.71%]	[0%, 13.02%]
Reoperation rate		
Sample Size	N = 13	N = 256
Proportion	0%	0.5%
95% CI	[0%, 24.71%]	[0%, 2.04%]

Table 7. da Vinci SP Lobectomy versus da Vinci Multiport Literature Comparison

Clinical Parameter	SP Thoracic Lobectomy Data K240502	da Vinci Multi-port Literature
Operative time		
Sample Size	N = 19	N = 9482
Mean +- SE	229.6 +- 14.71	255.7 +- 10.68
95% CI	[198.72, 260.55]	[233.05, 278.35]
Length of stay (days)		
Sample Size	N = 19	N = 94381
Mean +- SE	3.8 +- 1.02	4.98 +- 0.18
95% CI	[1.70, 5.98]	[4.61, 5.35]
Estimated blood loss		
Sample Size	N = 19	N = 381
Mean +- SE	47.9 +- 10.88	91.9 +- 7.90
95% CI	[25.04, 70.75]	[66.76, 117.03]

Clinical Parameter	SP Thoracic Lobectomy Data K240502	da Vinci Multi-port Literature
Intra-operative adverse event rate		
Sample Size	N = 19	N = 7637
Proportion	0%	3.84%
95% CI	[0%, 17.65%]	[2.65%, 5.03%]
Major adverse event rate (Clavien-Dindo III and IV)		
Sample Size	N = 19	N = 2581
Proportion	15.8%	7.06%
95% CI	[3.38%, 39.58%]	[1.48%, 12.65%]
Minor adverse event rate (Clavien/Dindo I and II)		
Sample Size	N = 19	N = 2581
Proportion	31.64%	35.27%
95% CI	[20.25%, 66.50%]	[27.10%, 43.44%]
Transfusion rate		
Sample Size	N = 19	N = 20447
Proportion	0%	2.80%
95% CI	[0%, 17.65%]	[0.78%, 4.82%]
Conversion rate		
Sample Size	N = 19	N = 9684
Proportion	0%	6.6%
95% CI	[0%, 17.65%]	[5.47%, 7.75%]
Mortality rate		
Sample Size	N = 19	N = 69004
Proportion	0%	1.25%
95% CI	[0%, 17.65%]	[1.05%, 1.45%]
Readmission rate		
Sample Size	N = 19	N = 37972
Proportion	5.3%	5.57%
95% CI	[0.13%, 26.03%]	[4.54%, 6.60%]
Reoperation rate		
Sample Size	N = 19	N = 9420
Proportion	0%	2.75%
95% CI	[0%, 17.65%]	[1.50%, 4.00%]

Exact 95% confidence intervals are provided for 9 discrete variables of the 12 parameters in the da Vinci SP system study.

The 95% confidence intervals for 9 discrete variables from the literature data are based on pooled proportions and exact method. The 95% confidence intervals for 3 continuous variables of the 12 variables from the literature data are based on weighted averages and weighted standard deviations where the sample means and standard deviations for each publication are taken as reported or estimated using quantiles as reported (McGrath et al. 2020).

VII. CONCLUSION

The Performance test data demonstrates that the ability of the subject device (SP1098) to perform general thoracoscopic surgical procedures, lobectomy and thymectomy. The Clinical Study results confirm that there are no different issues of safety or effectiveness as compared to the multiport IS4000 system when performing general thoracoscopic surgical procedures, lobectomy and thymectomy.

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

Table 8. Bibliography of Clinical Literature on da Vinci Multiport Thymectomy

1. Azenha, L. F., R. Deckarm, F. Minervini, P. Dorn, J. Lutz and G. J. Kocher (2021). "Robotic vs. Transsternal Thymectomy: A Single Center Experience over 10 Years." J Clin Med **10**(21).
2. Burt, B. M., X. Yao, J. Shrager, A. Antonicelli, S. Padda, J. Reiss, H. Wakelee, S. Su, J. Huang and W. Scott (2017). "Determinants of Complete Resection of Thymoma by Minimally Invasive and Open Thymectomy: Analysis of an International Registry." J Thorac Oncol **12**(1): 129-136.
3. Casiraghi, M., D. Galetta, A. Borri, A. Tessitore, R. Romano, D. Brambilla, P. Maisonneuve and L. Spaggiari (2018). "Robotic-assisted thymectomy for early-stage thymoma: a propensity-score matched analysis." J Robot Surg **12**(4): 719-724.
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