November 26, 2024

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

Re: K242318
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 1, 2024
Received: November 1, 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, colorectal, 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.

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,

BLETA VUNIQI -S

Digitally signed by BLETA VUNIQI -S
Date: 2024.11.26 15:28:57 -05'00'

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242318

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**: November 15, 2024

## II. SUBMITTER INFORMATION

| | |
|---|---|
| **Trade Name:** | da Vinci SP® Surgical System, Model SP1098,<br>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 (K240502)

**Reference Device**: da Vinci Xi Surgical System, Model IS4000,
EndoWrist Instruments, and Accessories (K171632)

## 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 “colorectal surgical procedures” to the indications, and to add “Low anterior resection / total mesorectal excision (LAR/TME), Colectomy (Right, Left, Transverse, Total, Hemi), Sigmoidectomy, and Abdominoperineal Resection (APR)” 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, 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

## 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 "colorectal surgical procedures" to the indication statement and to add "Low anterior resection / total mesorectal excision (LAR/TME), Colectomy (Right, Left, Transverse, Total, Hemi), Sigmoidectomy, and Abdominoperineal Resection (APR)" as new representative, specific procedures in the Professional Instructions for Use.

## VI. PERFORMANCE DATA

The addition of colorectal 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) or general thoracoscopic surgical procedures (K240502).

### 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 colorectal 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 colorectal surgical procedures. Each surgeon performed two (2) procedures in a cadaver model and one (1) procedure in a porcine model, for a total of 9 surgical procedures performed per system. 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 da Vinci Xi system, which is cleared for use in colorectal surgical procedures (K171632) and serves as a reference device for this 510(k).

**Table 1**

| Surgical Procedure | Subject | Procedure Completion Acceptance Criteria |
|---|---|---|
| Low Anterior Resection / Total Mesorectal Excision | Cadaver | • Sufficient colon mobilization to ensure tension-free anastomosis<br>• Complete mesorectal dissection (e.g., intact mesorectal fascial envelope, circumferential resection, distal dissection to levator ani)<br>• Critical anatomy identified (e.g., gonadal vessels, inferior mesenteric vessels, ureter, hypogastric nerves, pelvic nerves)<br>• Appropriate vessel ligation (e.g., inferior mesenteric or superior rectal vessels)<br>• Anastomosis complete and deemed surgically acceptable upon visual inspection<br>• Acceptable leak test (i.e., no air bubbles observed during leak test) |
| Right Hemicolectomy | Cadaver | • Sufficient colon mobilization to ensure tension-free anastomosis<br>• Critical anatomy identified (e.g., gonadal vessels, ureter, ileocolic vessels, colic vessels, duodenum)<br>• Appropriate vessel ligation (e.g., right colic, ileocolic, right branch of middle colic vessels)<br>• Anastomosis complete and deemed surgically acceptable upon visual inspection<br>• Acceptable leak test (i.e., no air bubbles observed during leak test) |
| Low Anterior Resection / Total Mesorectal Excision | Porcine | • Sufficient colon mobilization to ensure tension- free anastomosis<br>• Anastomosis complete and deemed surgically acceptable upon visual inspection<br>• Acceptable leak test (i.e. no air bubbles observed during leak test)<br>• Hemostasis maintained |

## Clinical Study

Intuitive conducted a prospective, multicenter, single-arm clinical study under an Investigational Device Exemption (IDE) to confirm the clinical safety and performance of the da Vinci SP Surgical System, Instruments and Accessories in colorectal surgical procedures. This study also confirms that use of the da Vinci SP Surgical System in colorectal surgical procedures does not raise different questions of safety or effectiveness. The study included 60 subjects (40 subjects in the United States and 20 subjects in South Korea) at eight (8) institutions in the United States and two (2) institutions in South Korea. The da Vinci SP Surgical System was used to perform the following procedures in this study:

- Low Anterior Resection with/without Total Mesorectal Excision (LAR/TME) (N = 29)
- Right Colectomy (N = 28)
- Other colorectal procedures (N = 3)
  - Sigmoid Colectomy (N = 2)
  - Transverse Colectomy (N=1)

### LAR/TME Results

Twenty-nine (29) subjects were enrolled in the study for LAR/TME with nineteen (19) subjects enrolled in the U.S. and ten (10) subjects enrolled in South Korea. Of these 29 subjects, 26 (89.7%) were malignant indications and 3 (10.3%) were benign indications. The mean BMI observed in the LAR/TME cohort was 25.7, with BMI in U.S. population was slightly higher (26.3) than the South Korean population (24.4).

All LAR/TME procedures in the study were completed using a da Vinci SP Surgical System without conversion to open or an alternative approach. Therefore, the conversion rate is 0% in the study for in the LAR/TME cohort.

There were no intraoperative adverse events and no unanticipated device-related adverse effects (UADE) reported for the LAR/TME cohort. There were eight (8) serious adverse events (SAE) reported, all deemed related to the colorectal procedure only and not related to the device. Of those eight (8) SAEs, three (3) were classified as major (all within Clavien-Dindo III classification). “Major” is defined by Clavien-Dindo Classification Grade IIIa or higher. **Table 2** summarizes the study results and **Table 3** lists the serious adverse events and major complications reported in the LAR/TME cohort.

**Table 2. Results Summary (LAR/TME)**

| Clinical Study Parameter | K242318 |
|---|---|
| Number of Subjects, n | 29 |
| Operative time (minutes), mean ± SE | 273.6 ± 14.84 |
| Estimated blood loss (mL), mean ± SE | 75.2 ± 16.12 |
| Blood transfusion rate, % | 0 |
| Conversion rate, % | 0 |
| Serious adverse event rate | 17.2% |
| Device-related serious adverse event rate, % | 0 |
| Intraoperative adverse event rate, % | 0 |
| Subjects with major AE (Clavien-Dindo Grade III/IV/V, n (%)) [a] | 3 (10.3%) |
| Length of hospital stay (days) [b], mean ± SE | 4.6 ± 3.69 |
| Rate of positive surgical margin, %, n= 7 | 0 |
| Readmission rate, % [c] | 4 (14.3%) |
| Reoperation rate, % | 0 |
| Mortality rate% | 0 |

**Notes**:
a. There were no grade IV or V events.
b. Mean length of hospital stay in the U.S. was 2.9 days and the mean length of hospital stay in South Korea was 7.7 days.
c. 4 subjects had unplanned re-admissions related to a SAE (3 classified as major and 1 classified as minor). None of the unpanned re-admissions were related to the da Vinci SP system.

**Table 3. Postoperative Serious Adverse Events and Major Complications (LAR/TME)**

| Type | Total study N= 29 |
|---|---|
| Subjects experiencing SAEs | 5 |
| Subject Experiencing Major AE Complications | 3 |
| Total Number of SAEs by Minor/Major Classification | 8 |
| Minor (All Clavien-Dindo Grade I) | |
| Acute Renal Failure | 1 |
| Dehydration | 1 |
| High Ileostomy Output | 1 |
| Ileus | 2 |
| Major (within Clavien-Dindo Grade III) | |
| Anastomotic Dehiscence | 1 |
| Bowel Obstruction | 1 |
| Hematoma of Presacral Space | 1 |

**Right Colectomy Results**

Twenty-eight (28) subjects were enrolled in the study for right colectomy, with eighteen (18) subjects enrolled in the U.S. and ten (10) subjects enrolled in South Korea. Of these 28 subjects, 22 (78.6%) were malignant indications and 6 (21.4%) was for a benign indication. The mean BMI observed in the Right Colectomy cohort was 25.8, with BMI in U.S. population was slightly higher (26.9) than the South Korean population (23.8), there was no statistical significance between the two regions.

All right colectomy procedures in the study were completed using a da Vinci SP Surgical System without conversion to open or an alternative approach, therefore, the conversion rate is 0% in the study for in the right colectomy cohort.

There was one (1) intraoperative adverse event (corneal abrasion) deemed not related to the colorectal procedure and/or device. There were no unanticipated device-related adverse effects (UADE). Two (2) Subjects experienced one (1) serious adverse event each, all relate to the colorectal procedure only and none classified as major AE complications (all Clavien-Dindo Grade I). **Table 4** summarizes the study results and **Table 5** lists the serious adverse events and major complications reported in the right colectomy cohort.

**Table 4. Results Summary (Right Colectomy)**

| Clinical Study Parameter | K242318 |
|---|---|
| Number of Subjects, n | 28 |
| Operative time (min), mean ± SE | 208.2 ± 11.43 |
| Estimated blood loss (mL), mean ± SE | 37.0 ± 8.4 |
| Transfusion rate, % | 0 |
| Conversion to open rate, % | 0 |
| Serious adverse event rate, % | 7.1 |
| Device-related serious adverse event rate, % | 0 |
| Intraoperative adverse event, % | 3.6% |
| Subjects with major adverse events, AE (Clavien-Dindo Grade III/IV/V), n (%) | 0 |
| Length of hospital stay (days), mean ± SE [a] | 3.5 ± 0.38 |
| Rate of positive surgical margins, n (%) | 0 |
| Readmission rate, n (%) | 0 |
| Reoperation rate% | 0 |
| Mortality rate, % | 0 |

Notes:

a. Mean length of hospital stay in the U.S. was 2.3 days and the mean length of hospital stay in South Korea was 5.8 days.

**Table 5. Postoperative Adverse Events (Right Colectomy)**

| Type | Total study N=19 |
|---|---|
| Subjects experiencing SAEs | 2 |
| Subject Experiencing Major AE Complications | 0 |
| Total Number of SAEs | 2 |
| Minor (Clavien-Dindo Grade I) | |
| Acute Renal Failure | 1 |
| Ileus | 1 |

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

Results of this study of da Vinci SP were compared to recently published clinical literature between 2010 and March 2024 on multiport robotic systems for LAR/TME and right colectomy procedures. Systematic literature searches were done for LAR/TME, and right colectomy 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 LAR/TME. **Table 7** summarizes the comparison in right colectomy. 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 (CI) 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 LAR/TME and right colectomy. 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 LAR/TME versus da Vinci Multiport Literature Comparison**

| Clinical Study Parameter | K242318 | da Vinci Multi-port Literature |
|---|---|---|
| Operative time | | |
| Sample Size | N = 29 | N = 11340 |
| Mean ± SE | 273.6 ± 14.84 | 282.3 ± 12.38 |
| 95% CI | [243.18, 303.99] | [256.43, 308.10] |
| Length of stay | | |
| Sample Size | N = 29 | N = 26500 |
| Mean ± SE | 4.6 ± 0.69 | 7.7 ± 0.79 |
| 95% CI | [3.15, 5.96] | [6.12, 9.37] |
| Estimated blood loss | | |
| Sample Size | N = 29 | N = 5055 |
| Mean ± SE | 75.2 ± 16.12 | 63.0 ± 14.66 |
| 95% CI | [42.22, 108.26] | [31.29, 94.63] |
| Intra-operative adverse event | | |
| Sample Size | N = 29 | N = 1739 |
| Proportion | 0% | 5.8% |
| 95% CI | [0%, 11.94%] | [2.95%, 8.72%] |
| Major adverse event complication rate (Clavien-Dindo III, IV, V) [a] | | |
| Sample Size | N = 29 | N = 9928 |
| Proportion | 10.3% | 8.1% |
| 95% CI | [2.19%, 27.35%] | [6.47%, 9.82%] |
| Anastomotic complication rate [b] | | |
| Sample size | N=29 | N=17204 |
| Proportion | 10.3% | 6.4% |
| 95% CI | [2.19%, 27.35%] | [4.75%, 7.97%] |
| Transfusion rate | | |
| Sample Size | N = 29 | N = 10332 |
| Proportion | 0% | 2.3% |
| 95% CI | [0%, 11.94%] | [1.35%, 3.22%] |
| Conversion rate | | |
| Sample Size | N = 29 | N = 48348 |
| Proportion | 0% | 6.2% |
| 95% CI | [0%, 11.94%] | [5.39%, 6.92%] |
| Mortality rate [c] | | |
| Sample Size | N = 28 | N = 36974 |
| Proportion | 0% | 0.6% |
| 95% CI | [0%, 12.34%] | [0.41%, 0.72%] |
| Readmission rate [c] | | |
| Sample Size | N = 28 | N = 30954 |
| Proportion | 14.3% | 7.1% |
| 95% CI | [4.03%, 32.67%] | [4.96%, 9.14%] |
| Reoperation rate [c] | | |
| Sample Size | N = 28 | N = 8107 |
| Proportion | 0% | 5.5% |
| 95% CI | [0%, 12.34%] | [4.37%, 6.59%] |

**Notes**:
a. There were no grade IV or V events.
b. Anastomoses were created using handheld, third-party laparoscopic staplers or were hand-sewn.
c. One subject missed their Day 42 visit due to a SAE.

**Table 7. da Vinci SP Right Colectomy versus da Vinci Multiport Literature Comparison**

| Clinical Parameter | K242318 | da Vinci Multi-port Literature |
|---|---|---|
| Operative time | | |
| Sample Size | N = 28 | N = 10907 |
| Mean ± SE | 208.2 ± 11.43 | 285.5 ± 26.92 |
| 95% CI | [184.76, 231.67] | [210.74, 360.25] |
| Length of stay (days) | | |
| Sample Size | N = 28 | N = 11164 |
| Mean ± SE | 3.5 ± 0.38 | 5.1 ± 0.28 |
| 95% CI | [2.75, 4.32] | [4.37, 5.81] |
| Estimated blood loss | | |
| Sample Size | N = 28 | N = 394 |
| Mean ± SE | 37.0 ± 8.40 | 98.7 ± 19.65 |
| 95% CI | [19.73, 54.20] | [0, 348.40] |
| Intra-operative adverse event rate | | |
| Sample Size | N = 28 | N = 520 |
| Proportion | 3.6% | 2.8% |
| 95% CI | [0.09%, 18.35%] | [0%, 29.23%] |
| Major adverse event rate (Clavien-Dindo III, IV, V) | | |
| Sample Size | N = 28 | N = 3203 |
| Proportion | 0% | 6.7% |
| 95% CI | [0%, 12.34%] | [5.55%, 7.93%] |
| Anastomotic complication rate [a] | | |
| Sample size | N=28 | N=14926 |
| Proportion | 0% | 4.2% |
| 95% CI | [0%, 12.34%] | [2.53%, 5.79%] |
| Transfusion rate | | |
| Sample Size | N = 28 | N = 2883 |
| Proportion | 0% | 7.3% |
| 95% CI | [0%, 12.34%] | [4.47%, 10.11%] |
| Conversion rate | | |
| Sample Size | N = 28 | N = 25893 |
| Proportion | 0% | 6.0% |
| 95% CI | [0%, 12.34%] | [5.12%, 6.88%] |
| Mortality rate | | |
| Sample Size | N = 28 | N = 11684 |
| Proportion | 0% | 0.6% |
| 95% CI | [0%, 12.34%] | [0.33%, 0.89%] |
| Readmission rate | | |

| | | |
|---|---|---|
| Sample Size | N = 28 | N = 11236 |
| Proportion | 0% | 6.8% |
| 95% CI | [0%, 12.34%] | [5.53%, 8.01%] |
| Reoperation rate | | |
| Sample Size | N = 28 | N = 9382 |
| Proportion | 0% | 5.8% |
| 95% CI | [0%, 12.34%] | [4.96%, 6.56%] |
| The 95% confidence intervals for 9 discrete variables from the literature data are based on pooled proportions and exact method. The weighted averages and 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). | | |
| Notes: a. Third-party handheld laparoscopic staplers were used in the creation of the anastomosis. | | |

## VII. CONCLUSION

The Performance test data demonstrates that the ability of the subject device (SP1098) to perform colorectal surgical procedures, LAR/TME and right colectomy. The Clinical Study results confirm that there are no different issues of safety or effectiveness as compared to the multiport da Vinci system when performing colorectal surgical procedures, LAR/TME and right colectomy.

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 LAR/TME (n=55)**


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**Table 9. Bibliography of Clinical Literature on da Vinci Multiport Right Colectomy (n=18)**


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