December 2, 2025

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

Re: K252069
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 3, 2025
Received: November 3, 2025

Dear Mike Yramategui:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.12.02 15:11:42 -05'00'

Mark Trumbore Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252069

Please provide the device trade name(s).

da Vinci SP Surgical System (SP1098)

Please provide your Indications for Use below.

da Vinci SP Surgical System, Model SP1098:
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci SP Surgical System, Model SP1098) is intended to assist in the accurate control of Intuitive Surgical da Vinci SP Instruments during urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is also indicated for use in cholecystectomy, inguinal hernia repair, and appendectomy procedures. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

da Vinci SP Instruments:
Intuitive Surgical da Vinci SP Instruments are controlled by the da Vinci SP Surgical System, Model SP1098, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. The system is indicated for urologic, colorectal, and general thoracoscopic, surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is also indicated for use in cholecystectomy, inguinal hernia repair, and appendectomy procedures. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary [21 CFR § 807.92(c)]

I. SUBMITTER INFORMATION

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

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

Date Summary Prepared: December 1, 2025

II. SUBMITTER INFORMATION

Trade Name:	da Vinci SP® Surgical System, Model SP1098, da Vinci SP® Instruments, and Accessories
Common Name:	System, Surgical, Computer Controlled Instrument
Classification Name:	Endoscope and Accessories (21 CFR §876.1500)
Regulatory Class:	Class II
Product Code:	NAY (System, Surgical, Computer Controlled Instrument)
Submission Type:	Traditional 510(k)

III. PREDICATE DEVICE INFORMATION

Predicate Device: da Vinci SP Surgical System, Model SP1098,
da Vinci SP Instruments, and Accessories (K243714)

Reference Device: da Vinci Xi Surgical System, Model IS4000,
EndoWrist Instruments, and Accessories (K131861)

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 an endoscope, instruments, and accessories.

The surgeon seated at the Surgeon Console controls all movement of the instruments and endoscope by using two hand controls and a set of foot pedals. The surgeon views the endoscopic image on a three-dimensional (3D) viewer, which provides a view of patient anatomy and instrumentation, along with icons and other user interface features.

The Vision Cart includes supporting electronic equipment, such as the light source, video and image processing, and the networking hardware. The Vision Cart also has a touchscreen to view the endoscopic image and adjust system settings.

The Patient Cart is the operative component of the da Vinci SP Surgical System. Its primary function is to support the positioning of the surgical port and to manipulate the surgical instruments and endoscope. The Patient Cart is positioned 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 endoscope. The patient-side assistant installs and removes the endoscope and instruments intra-operatively.

This 510(k) is for a labeling modification only, to add "cholecystectomy, inguinal hernia repair, and appendectomy" to the cleared labeling.

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 also indicated for use in cholecystectomy, inguinal hernia repair, and appendectomy procedures. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

da Vinci SP Instruments:
Intuitive Surgical da Vinci SP Instruments are controlled by the da Vinci SP Surgical System, Model SP1098, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. The system is indicated for urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is also indicated for use in cholecystectomy, inguinal hernia repair, and appendectomy procedures. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for use.

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

The da Vinci SP Surgical System, Model SP1098 and da Vinci SP Instruments and Accessories are unchanged from the predicate device in terms of intended use, design, performance, and technological characteristics. The labeling has been changed to add ""cholecystectomy, inguinal hernia repair, and appendectomy procedures" to the indication statement and to add "cholecystectomy, inguinal hernia repair, and appendectomy" as new representative, specific procedures in the Professional Instructions for Use.

VI. PERFORMANCE DATA

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

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 system for performing cholecystectomy and inguinal hernia repair procedures. Human 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 and external, board-certified surgeons participated in a pre-clinical study using the SP1098 system to perform cholecystectomy and inguinal hernia repair procedures. Each surgeon performed a total of two (2) procedures (inguinal hernia repair, cholecystectomy) in a cadaver and porcine model, for a total of 4 surgical procedures performed by each of the three surgeons. Acceptance criteria for successful completion of each procedure are listed below (**Table 1**). Surgical safety was evaluated by assessing the number and severity of device-related adverse events occurring during the procedures. Physiologic measurements taken in the porcine portion of the study were assessed by analyzing if a clinically significant change in blood pressure, heart rate, or blood volume associated with a surgical event were observed. In addition, surgeons completed questionnaires that evaluated their ability to perform surgical tasks using the SP1098 and the multiport da Vinci system, which is cleared for use in cholecystectomy and inguinal hernia repair procedures (K131861) and serves as a reference device for this 510(k).

Table 1: Acceptance Criteria for Successful Procedure Completion in Cadaver and Porcine

Surgical Procedure	Subject	Procedure Completion Acceptance Criteria
Inguinal hernia repair	Cadaver	• Cord structures, inferior epigastric and femoral vessels, and Cooper's ligament identified • Preperitoneal dissection provides enough space for mesh • Mesh covers inguinal ring, indirect triangle, and femoral ring • Mesh lies flat with no bunching following suture fixation • Suture fixation of mesh: suture tightened such that there is no gap between suture and mesh • Peritoneum closure: mesh is completely covered by peritoneum
	Porcine	• Prepubic tendon (equivalent of Cooper's ligament) identified • Preperitoneal dissection provides enough space for mesh • Mesh covers inguinal canal • Mesh lies flat with no bunching following suture fixation • Suture fixation of mesh: suture tightened such that there is no gap between suture and mesh • Peritoneum closed over mesh • Hemostasis maintained
Cholecystectomy	Cadaver	• No duct injury upon visual inspection of the dissected anatomy • Critical view demonstrated: clear view of only the cystic duct and artery entering the gall bladder • Gall bladder freed from liver bed
	Porcine	Same as above plus: • Hemostasis maintained

The addition of appendectomy as a new representative, specific procedure in the Professional Instructions for Use is based on appendectomy being a covered procedure under the umbrella procedure of Low Anterior Resection Total Mesorectal Excision (LAR/TME), covered procedure Colectomy, and the following:

1. All procedural steps, surgical tasks, and instruments required to perform appendectomy with the da Vinci SP Surgical System are part of the umbrella procedure.
2. Appendectomy is less complex and less challenging than the umbrella procedure.

3. All anatomical structures encountered in appendectomy are encountered similarly in the umbrella procedure.
4. Use of the da Vinci SP Surgical Systems to perform appendectomy does not introduce any different issues of safety or effectiveness as compared to device usage in the cleared umbrella procedure.

The appendix is a small, tube-like structure that is attached to the Cecum of the large intestine. The appendix is removed during an appendectomy procedure, commonly used to treat appendicitis. It is also removed *en bloc* with the specimen during a right colectomy procedure, which is a covered procedure under the umbrella procedure Low Anterior Resection Total Mesorectal Excision (LAR/TME) which was cleared under K242318. A comparison of the surgical tasks performed with the da Vinci Surgical Systems for appendectomy shows that there are no new surgical tasks introduced by the appendectomy as compared to the colorectal umbrella procedure of LAR/TME and covered procedure Colectomy. All these procedures share the same surgical tasks in the same anatomical location of the abdomen.

The surgical risks associated with appendectomy are not different than those associated with Low Anterior Resection Total Mesorectal Excision (LAR/TME) and Colectomy. They include: 1) bleeding; 2) infection; 3) leak; 4) stricture; 5) bowel injury; 6) injury to adjacent organs; and 7) perforation.

Appendectomy can be completed using the da Vinci SP Surgical System without introducing any different issues of safety or effectiveness as compared to the representative, specific surgical procedures previously cleared for the da Vinci SP system. The addition of appendectomy as a representative, specific procedure does not represent a change or modification in the device that could significantly affect the safety or effectiveness of the device, thus requiring no new clinical data or other validation/verification testing to evaluate safety or effectiveness of the device.

Published Clinical Data

Published clinical data comparing cholecystectomy and inguinal hernia repair using the da Vinci SP system to the da Vinci multiport systems (da Vinci MP) were also provided. Peer-reviewed literature published between January 1, 2018 and March 3, 2025 on robotic-assisted general laparoscopic surgery using the da Vinci SP system were identified by systematically searching the PubMed, Scopus and Embase databases. After systematic screening by the representative procedures in this submission, the publications used for comparison to the SP literature are as follows:

- For cholecystectomy, 9 SP publications[1-4,6-10] with LOE 3-4 for 1512 patients are included for data extraction and summarized to compare with MP literature.
- For inguinal hernia repair, 4 SP publications[1,3,5,11] with LOE 3-4 for 451 patients are included for data extraction and summarized to compare with MP literature.

For da Vinci MP, the literature review focused specifically on recent publications from 2023 to 2024 to represent the most current clinical landscape. Emphasis is placed on high-quality evidence derived from large patient populations to ensure robust and relevant findings.

- For cholecystectomy, 6 MP publications[2,4,5,7,9,10] with LOE 2 for 134,698 patients are included for data extraction and summarized to provide the basis for comparison with SP literature.
- For inguinal hernia repair, 9 MP publications[1,3,5,6,8,9,11-13] with LOE 2-3 for 6,492 patients are included for data extraction and comparison with SP.

Tables 2 - 4 includes the ranges of average values or rates extracted for each clinical outcome for comparison between approaches and demonstrates similar ranges of outcomes between da Vinci SP and da Vinci MP. A listing of the publications for da Vinci SP is provided in **Bibliography for SP Literature** and a listing of the publications for da Vinci MP is provided in **Bibliography for MP Literature**.

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 for these labeling changes.

Bench testing demonstrates the ability of the da Vinci SP Surgical System to perform the representative procedures as substantially equivalent to the da Vinci Multiport system as a reference device (K131861). A review of the published literature provides additional confirmation that outcomes of representative surgical procedures with the da Vinci SP Surgical System are substantially equivalent to the da Vinci Multiport system as a reference device (K131861) 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 2: SP Cholecystectomy vs. MP Literature Comparison

	SP Cholecystectomy [a]	**MP Cholecystectomy** [b]
# Included Publications (Total Patient Count)	9 publications[1-4,6-10], 1512 patients	6 publications[2,4,5,7,9,10], 134,698 patients
Average Operative Time (minutes)	**21.89**[2,3] **– 126**[2]	**82.9**[10] **– 128.4**[2]
Average EBL (mL)	**2**[2] **– <50**[2]	NR
Transfusion Rate (%)	**0%**[6,10]	**2.0%**[2]
Conversion to Open Surgery (%)	**0%**[1,3,4,7,9,10] **– 0.89%**[2]	**0.8%**[10] **– 1.9%**[2]
Intraoperative Complication Rate (%)	**0%**[1,2,3] **– 3.3%**[4]	**0.3%**[2]
30-day Postoperative Complication Rate (%)	**0%**[2,4,6,8,10] **– 10.6%**[3]	**10.5%**[5] **– 20.5%**[7]
Major (C-D grade ≥ III) Complication Rate (%)	**0%**[1] **— 0.7%**[7]	**2.6%**[10] **– 9.71%**[4]
Average Length of Hospital Stay (days)	**0.28**[2] **– 2.4**[10]	**0.64**[10] **– 3.6**[2]
Re-admission Rate (%)	**1.4%**[1] **– 1.9%**[6]	**3.6%**[10] **– 5.5%**[2]
Re-operation Rate (%)	**0%**[1]	**0.6%**[10] **– 1.9%**[2]
Mortality Rate (%)	**0%**[1]	**0.05%**[5] **– 0.5%**[2]
Patient Characteristics		
Average Age	**41**[1] **– 47.7**[10]	**49.7**[10] **– 71.2**[7]
Sex (Male)	**24.8%**[9] **– 45.8%**[8]	**29.7%**[10] **– 45.5%**[7]
Average BMI	**23.3**[9] **– 33.9**[1]	Average NR; (obesity or BMI ≥30: 21.1%[7] — 57.6%[10])
ASA Class	I: **0%**[10] **– 87.0%**[3] II: **13.0%**[3] **– 96.0%**[10] III: **0%**[3,6,8] **— 26.9%**[1] IV: **0%**[3,4,6-10] **— 0.7%**[1]	NR
Additional Outcomes		
Average Follow-up Time (month)	**5.37**[3] **– 8.9**[1]	**1**[2] **– 12**[7]
Bile Duct Injury Rate (%)	**0%**[3,6]	**0.2%**[2] **– 0.7%**[7]
Incisional Hernia Rate (%)	**0%**[9,10] **– 1.4%**[1,3]	NR
Other Complications reported >1%	Wound seroma: **2.4%**[9] **— 3.2%**[3] Wound infection: **5.1%**[3]	Sepsis/septic shock: **4.6%**[2] Intestinal obstruction: **2.0%**[2] Wound disruption/dehiscence: **1.5%**[2] Pulmonary complications: **4.1%**[2] Cardiovascular complications: **1.7%**[2]

[a] da Vinci Single Port (SP) publications from January 1, 2018 – March 3, 2025 on cholecystectomy with LOE 1-4 and relevant results were included.

[b] da Vinci multiport (MP) Publications from 2023 – 2024 on cholecystectomy with LOE 1-2 and relevant results were included.

C-D: Clavien-Dindo; EBL: Estimated Blood Loss; LOE: Level of Evidence; NR: Not Reported; POD: Postoperative day.

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.

Table 3: SP Inguinal Hernia Repair vs. MP Literature Comparison

	SP Inguinal Hernia Repair [a]	MP Inguinal Hernia Repair [b]
# Included Publications (Total Patient Count)	4 publications[1,2,5,11], 451 patients	9 publications[1,3,5,6,8,9,11-13], 6,492 patients
Average Operative Time (minutes)	**60**[2] **– 79.1**[1]	**86.5**[13] **– 160**[6]
Average EBL (mL)	**3**[11]	**14.5**[13] **— 50**[6]
Transfusion Rate (%)	NR	**0%**[3]
Conversion to Open Surgery (%)	**0%**[1,5,11]	**0%**[3] **– 2.4%**[9]
Intraoperative Complication Rate (%)	**0%**[1,2,5,11]	**0%**[1,3,6,12]
30-day Postoperative Complication Rate (%)	**0%**[2] **– 16%**[11,c]	**3.8%**[3] **– 20.3%**[5]
Major (C-D grade ≥ III) Complication Rate (%)	**0%**[1,11,c]	Complication requiring intervention: **0.7%**[12] **— 4.5%**[1]
Average Length of Hospital Stay (days)	**0**[1,2,5,11] **– 1**[2]	**1.54**[3] **– 2.70**[5]
Re-admission Rate (%)	**1.3%**[1] **– 2.3%**[5]	**0%**[3] **– 8%**[6]
Re-operation Rate (%)	**0%**[1,5,11]	**0%**[3] **– 2.0%**[1]
Mortality Rate (%)	**0%**[1,5,11]	**0%**[1,3,13] **– 0.3%**[5]
Patient Characteristics		
Average Age	**52.1**[1] **– 56**[11]	**52.74**[13] **– 65**[12]
Sex (Male)	**91%**[11] **– 93.5%**[1]	**82.1%**[5] **– 100%**[6,13]
Average BMI	**25.8**[11] **– 27.3**[1]	**25.7**[11] **– 28.32**[13]
ASA Class	I: **17%**[11] **– 22.1%**[1] II: **55%**[11] **– 58.4%**[1] III: **19.5%**[1] **— 27%**[11] IV: **0%**[1] **— 1.1%**[5]	I: **10.5%**[13] **— 28.9%**[11] II: **56.4%**[11] **— 62%**[8] III: **14.7%**[11] **— 31.6%**[13] IV: **1%**[8,11,13] I-II: **88.2%**[3] III-IV: **11.8%**[3]
Additional Outcomes		
Average Follow-up Time (month)	**1**[2,11] **– 13.3**[5]	**3**[3] **– 69**[11]
Hernia Recurrence Rate (%)	**0%**[1,5]	**0%**[11,13] **– 2.29%**[11]
Incisional Hernia Rate (%)	**1.3%**[1] **– 2.3%**[5]	NR
Other Complications reported >1%	Seroma: **3.4%**[5] **— 3.9%**[1] Ileus: **1.1%**[5] **— 1.3%**[1] Obstructive AKI: **1.1%**[5] Urinary retention: **1.1%**[5] UTI: **1.1%**[5] **— 1.3%**[1]	Hematoma: **2.9%**[1] **— 3.95%**[11] Ileus: **4%**[6] Infected lymphocele with IR drainage: **2.5%**[6] Pain: **7.3%**[1] Persistent pain: **5%**[13] Seroma: **4%**[8] **— 6.5%**[1] Surgical site occurrence or infection: **5.2%**[12] Urinary retention: **5%**[13] Complication requiring procedure: **4.5%**[1] Other complication: **4.5%**[1]

[a] da Vinci Single Port (SP) publications from January 1, 2018 – March 3, 2025 on inguinal hernia repair with LOE 1-4 and relevant results were included.

[b] da Vinci multiport (MP) Publications from 2023 – 2024 on inguinal hernia repair with LOE 1-2 and LOE 3 (with robotic sample size > 200) and relevant results were included.
[c] One SP study reported 30-day complications C-D grade I-IIIa of 16% and grade IIIb-IV of 0%.[11]
AKI: Acute Kidney injury; C-D: Clavien-Dindo; EBL: Estimated Blood Loss; IR: Interventional Radiology; LOE: Level of Evidence; NR: Not Reported; POD: Postoperative day; UTI: Urinary tract infection.
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 Literature: Literature for Cholecystectomy and Inguinal Hernia Repair with da Vinci Single Port (SP) Surgical System (n=11)

1. Bianco FM, Dreifuss NH, Chang B, et al. Robotic single-port surgery: Preliminary experience in general surgery. *International Journal of Medical Robotics and Computer Assisted Surgery.* 2022;18(6):e2453.
2. Celotto F, Ramacciotti N, Mangano A, et al. Da Vinci single-port robotic system current application and future perspective in general surgery: A scoping review. *Surgical Endoscopy.* 2024;38(9):4814-4830.
3. Choi YJ, Sang NT, Jo HS, Kim DS, Yu YD. A single-center experience of over 300 cases of single-incision robotic cholecystectomy comparing the da Vinci SP with the Si/Xi systems. *Scientific Reports.* 2023;13(1):9482.
4. Cruz CJ, Huynh F, Kang I, Lee WJ, Kang CM. Initial experiences of robotic SP cholecystectomy: A comparative analysis with robotic Si single-site cholecystectomy. *Ann Surg Treat Res.* 2021;100(1):1-7.
5. Dreifuss NH, Chang B, Schlottmann F, et al. Robotic inguinal hernia repair: is the new Da Vinci single port platform providing any benefit? *Surgical Endoscopy.* 2022;37(3):2003-2013.
6. Kang YH, Kang JS, Cho YS, et al. A retrospective multicentre study on the evaluation of perioperative outcomes of single-port robotic cholecystectomy comparing the Xi and SP versions of the da Vinci robotic surgical system. *Int J Med Robot.* 2021;18(1):e2345.
7. Kim WJ, Choi SB, Kim WB. Feasibility and Efficacy of Single-Port Robotic Cholecystectomy Using the da Vinci SP® Platform. *JSLS.* 2022;26(2).
8. Park SE, Hong TH. Gasless robotic single-port cholecystectomy using the DaVinci SP system: A feasible way to minimise surgical derangement while obtaining critical view of safety. *International Journal of Medical Robotics and Computer Assisted Surgery.* 2023:e2547.
9. Rho SY, Choi M, Kim SH, et al. ArtiSential laparoscopic cholecystectomy: a comparative analysis with robotic single-port cholecystectomy. *Ann Surg Treat Res.* 2024;107(6):336-345.
10. Park JI, Chung YK, Lee YM, Nam CW, Nah YW. Comparative analysis of postoperative outcomes of single-incision cholecystectomy: Propensity score matching of robotic surgery using the da Vinci SP system and da Vinci Xi system vs. laparoscopic surgery. Ann Hepatobiliary Pancreat Surg. 2025.

11. Celotto F, Ramacciotti N, Danieli G, et al. Learning Curve for Robotic Inguinal Hernia Repair With da Vinci Single-Port Robotic System. *Surg Innov.* 2025:15533506251314605.

Bibliography for MP literature: Literature for Cholecystectomy and Inguinal Hernia Repair with da Vinci Multiport (MP) Surgical System (n=13)

1. Baginski B, Tran D, Ogola G, Arnold D. A single-center retrospective review of laparoscopic totally extraperitoneal versus robotic transabdominal preperitoneal inguinal hernia repair. Baylor Univ Med Cent Proc. 2024.
2. Campbell S, Lee SH, Liu Y, Wren SM. A retrospective study of laparoscopic, robotic-assisted, and open emergent/urgent cholecystectomy based on the PINC AI Healthcare Database 2017-2020. World J Emerg Surg. 2023;18(1):55.
3. Chao TC, Tung HY, Tsai CH, et al. Laparoscopic versus robotic TAPP/TEP inguinal hernia repair: a multicenter, propensity score weighted study. Hernia. 2024;28(1):199-209.
4. Charland N, Hadaya J, Mallick S, et al. National trends and outcomes of robotic emergency general surgery in the United States. Surgery (United States). 2024;176(3):835-840.
5. Grimsley EA, Janjua HM, Herron T, et al. Patient outcomes and cost in robotic emergency general surgery. J Robot Surg. 2023;17(6):2937-2944.
6. Jaber AR, Moschovas MC, Rogers T, et al. Simultaneous hernia repair following robotic-assisted radical prostatectomy is safe with low rates of mesh-related complications. J Robot Surg. 2023;17(4):1653-1658.
7. Kalata S, Thumma JR, Norton EC, Dimick JB, Sheetz KH. Comparative Safety of Robotic-Assisted vs Laparoscopic Cholecystectomy. JAMA Surg. 2023.
8. Lima DL, Nogueira R, Dominguez Profeta R, et al. Current trends and outcomes for unilateral groin hernia repairs in the United States using the Abdominal Core Health Quality Collaborative database: A multicenter propensity score matching analysis of 30-day and 1-year outcomes. Surgery. 2024;175(4):1071-1080.
9. Lunardi N, Abou-Zamzam A, Florecki KL, et al. Robotic Technology in Emergency General Surgery Cases in the Era of Minimally Invasive Surgery. JAMA surgery. 2024;159(5):493-499.
10. Maegawa FB, Stetler J, Patel D, et al. Robotic compared with laparoscopic cholecystectomy: A National Surgical Quality Improvement Program comparative analysis. Surgery (United States). 2024;178:108772.
11. Valorenzos A, Nielsen KA, Inan I, et al. Reduced risk of recurrence following robotic-assisted TAPP for inguinal hernia repair compared to laparoscopic TAPP: a cohort study of 395 cases. Hernia. 2024;29(1):33.

12. Varvoglis DN, Sanchez-Casalongue M, Olson MA, et al. Comparison of post-operative outcomes of large direct inguinal hernia repairs based on operative approach (open vs. laparoscopic vs. robotic) using the ACHQC (Abdominal Core Health Quality Collaborative) database. Surgical Endoscopy. 2022.
13. Wikiel KJ, Bollinger D, Montero PM, Jones TS, Robinson TN, Jones EL. Stray energy injury during robotic versus laparoscopic inguinal hernia repair: a randomized controlled trial. Surgical Endoscopy. 2023;37(11):8771-8777.