A Prospective, Multi-Center Investigation of the *da Vinci SP*® Surgical System in Colorectal Procedures for Benign and Malignant Disease

Protocol Summary

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Study #	dV SP – CR-01
Title	A prospective, multi-center investigation of the *da Vinci SP*® Surgical System in colorectal procedures for benign and malignant disease.
Study Design	A prospective, multi-center, single-arm clinical investigation
Study Center	Up to twelve (12) institutions will be included with up to 9 institutions from the United States (US) and up to 3 institutions from South Korea (Appendix II)
Number of Subjects	The study will enroll a maximum of 60 subjects, including 30 subjects who undergo low anterior resection (LAR) with or without total mesorectal excision (TME), and 30 subjects who undergo right colectomy.
Study Objective	To confirm the safety and performance of the *da Vinci SP* Surgical System, Instruments and Accessories in a complex colorectal procedures such as low anterior resection (LAR) with or without total mesorectal excision (TME). An additional 30 cases of right colectomy will be studied to obtain data on the use of the SP system in a different anatomical location, as suggested by FDA in G20060/S001. Data from these two procedures will be used to support a colorectal indication for the *da Vinci SP* Surgical System.
Premarket Study Primary Endpoints	<u>Primary Performance:</u> • The primary performance endpoint will be assessed as the ability to complete the planned *da Vinci SP*-assisted LAR/TME or right colectomy procedure without conversion to an alternate approach. Conversion to an alternate approach comprises conversion to open, multiport laparoscopic, multiport robotic or hand-assisted approach requiring undocking of the *da Vinci SP* Surgical System in order to complete the planned procedure using the alternate approach. <u>Primary Safety:</u> • The primary safety endpoint will be assessed as the incidence of all intraoperative and post-operative adverse events that occur through the 42-day follow-up period for LAR/TME and right colectomy cases Performance and safety endpoints will be analyzed and reported separately for LAR/TME and right colectomy cases
Premarket Study Secondary Endpoint	<u>For malignant cases:</u> • Rate of positive circumferential resection margin (CRM), rate of positive distal resection margin (DRM), and lymph node yield will be evaluated

Premarket Additional Outcomes of Interest	• Operative time (total time to complete the colorectal procedure; including total time using the *da Vinci SP* Surgical System)
	• Estimated blood loss (EBL)
	• Blood transfusions rate
	• Length of hospital stay (LOS)
	• Conversion and adverse event rates for right colectomy cases
	• Mortality rate through 42 days
	• Unplanned procedure-related readmission rate through 42 days
	• Unplanned procedure-related reoperation rate through 42 days
	• Other pathological outcomes for malignant cases
	• Other anticipated colorectal clinical outcomes to be summarized:
	  o Incidence of: anastomotic leak, bowel fistula, perforation, wound infections, use of diverting ileostomy through 42 days
	  o Rates of: sexual dysfunction in men, painful intercourse in women through 42 days
	  o Bowel recovery outcomes measured as time to: first bowel movement, first flatus, return to clear diet, low residue diet and regular diet
	• Patient reported outcomes such as International Index Erectile Function (IIEF) and the Abbreviated Sexual Function Questionnaire (ASFQ) are recommended but optional if patient refuses to complete and will be collected preoperatively and at approximately 42-day follow up for LAR/TME cases

Post-Market Long Term Data Collection	Long-term annual data out to 5 years will be collected from study subjects that underwent LAR/TME or right colectomy for malignant conditions. This data collection will include information on long-term cancer outcomes such as local recurrence, disease free survival, overall survival, any administered adjuvant therapy, and adverse events related to the index procedure. Annual follow-up to assess sexual function via patient reported outcomes using IIEF and ASFQ in LAR/TME cases will also be collected through 5 years.
Study Eligibility Criteria	**<u>Inclusion Criteria:</u>** • Age ≥ 18 years • BMI ≤ 35 • Candidate for single-port robotic-assisted surgery for low anterior resection with or without total mesorectal excision or for right colectomy procedures • ASA ≤ 3 • Willing and able to provide a written informed consent document. • Willing and able to comply with the study protocol requirements including perioperative follow-up examinations at 14 days and 42 days post operatively, and post-market long-term follow-up on an annual basis through 5 years **<u>Exclusion Criteria:</u>** • Clinical or radiological evidence of distant metastatic disease. Subjects with regional lymph node involvement can be enrolled.

	• Life expectancy less than 6 months • Cancer of the anal canal requiring an abdominoperineal resection. • Preoperative colonoscopy demonstrating synchronous colorectal cancer • Subjects with threatened mesorectal margins (≤ 1mm) on MRI or ultrasound (for LAR ONLY) • Subjects with planned major concomitant procedures (eg. hepatectomaies, other intestinal resections) or emergent case • Subjects undergoing both LAR/TME and right colectomy during the same operation • History of inflammatory bowel disease • Subject has a known bleeding or clotting disorder • Uncontrolled illness including, but not limited to ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements • Subject is contraindicated for general anesthesia or surgery • Subject had prior incisional hernia with mesh repair • Subject belongs to vulnerable population • Subject is pregnant or suspected to be pregnant **Intraoperative Exclusion Criteria** • Subject presents with adhesions or scarring in the pelvis which in the opinion of the investigator limits the ability to perform the minimally invasive procedure
Study Assessments	**Pre Market Assessments**: Pre-operative Assessment: Subject demographics, neoadjuvant therapy, diagnostic tests to determine disease status and subject eligibility; patient reported outcomes (IIEF/ASFQ) in LAR/TME cases Intra-Operative Assessments: Assessment of ability to complete surgical procedures (conversion to an alternate approach), total operative time, robotic procedure time, estimated blood loss (EBL), the incidence of blood transfusions, use of diverting ileostomy and intra-operative adverse events Post-Operative (prior to discharge) Assessment: Length of hospital stay, in-hospital mortality, reoperation, bowel recovery outcomes and postoperative adverse events Post-Operative (14 ± 3 days) Assessment: Final pathology outcomes, unplanned procedure-related readmission and reoperation, mortality, postoperative adverse events Post-Operative (42 days ± 7 days) Assessment: Unplanned procedure-related readmission and reoperation, mortality, postoperative adverse events; patient reported outcomes (IIEF/ASFQ) in LAR/TME cases **Post Market Assessments:** Annual Assessment through 5-years (± 90 days): local cancer recurrence, disease free survival, overall survival and adjuvant therapy; adverse events

	related to index procedure and patient reported outcomes (IIEF/ASFQ) in LAR/TME cases.
Study Devices	System: *da Vinci SP* Surgical System Instruments: The EndoWrist SP Instruments include: a needle driver, medium-large clip applier, monopolar curved scissors, monopolar cautery instrument, fenestrated bipolar forceps, Maryland bipolar forceps, Cadiere forceps, round tooth retractor and the Camera Instrument with Firefly imaging system. Accessories: The SP Accessories include: Cannula, Obturator, Entry Guide Kit, Sheaths for Camera and Instruments, tips for Monopolar Curved Scissors, Cautery Hook and Cautery Spatula, Instrument Arm Drape, cautery cords, and SP Access Port Kit.
Sample Size Considerations	The recommended number of evaluable subjects for LAR/TME in this confirmatory study (N=30) reflects the anticipated intraoperative and post-operative adverse event rate based on prior literature of LAR/TME performed by da Vinci Xi Surgical Systems. It is intended to provide a measure by which the performance and safety of the *da Vinci SP* Surgical System in a clinical setting can be confirmed based on demonstrating equivalence with the *da Vinci Xi*® Surgical System via animal and cadaver testing. An additional 30 cases of right colectomy will be enrolled to obtain data on the use of the SP system in a different anatomical location, as suggested by FDA in G20060/S001. Therefore, a total of N=60 subjects are planned in this confirmatory study.
Data Analysis	All evaluable subjects will be included for analysis regardless of the completeness of their data. Analyses will be based on pre-operative characteristics, intra-operative and post-operative characteristics, and outcomes through 42 days follow-up. Data from both geographies will be reported in aggregates as well as by geography for each procedure.
Study Enrollment & Follow Up	Enrollment is anticipated to take approximately 18 months. ***Premarket Assessment:*** Subjects will be followed postoperatively at 14 days (± 3 days) and at 42 days (± 7 days). ***Postmarket Assessment:*** Subjects with malignant tumors will be followed on an annual basis out to 5 years (± 90 days) post-operatively