DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 19, 2017

Intuitive Surgical, Inc.
% Ms. Cindy Domecus
Chief Regulatory Advisor, Intuitive Surgical
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K161178
Trade/Device Name: Da Vinci Xi Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 22, 2016
Received: April 26, 2016

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161178

Device Name
da Vinci Surgical System, Model IS4000, and EndoWrist Instruments and Accessories

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model lS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endloscopic dissectors, scissors, scalpels, 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, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used 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.

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510(k) Summary (21 CFR § 807.92(c))

I. SUBMITTER INFORMATION

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

Contact: Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Chief Regulatory Advisor to Intuitive Surgical
Telephone: 650.343.4813
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Email: domecusconsulting@comcast.net

Date Summary Prepared: January 18, 2017

II. SUBJECT DEVICE INFORMATION

Device Trade Name: *da Vinci*® Surgical System, Model IS4000
Common Name: System, Surgical, Computer Controlled Instrument
Classification Name: Endoscope and Accessories (21 CFR §876.1500)
Regulatory Class: II
Product Code: NAY
Submission Type: Traditional 510(k)

III. PREDICATE DEVICE INFORMATION:

Predicate Device: Intuitive Surgical *da Vinci* Surgical System, Model IS4000 (K131861, K152578)
Intuitive Surgical *da Vinci* Surgical System, Model IS3000 (K081137, K123463, K090993)

IV. DEVICE DESCRIPTION:

This 510(k) is for a labeling modification only, to include the following additional representative, specific procedures under the cleared "urologic surgical procedures" general indication for the *da Vinci Xi* Surgical System (K131861): Prostatectomy (Radical), Nephrectomy (Partial, Radical), and Cystectomy (Radical, Partial), Donor Nephrectomy, Cyst Removal, Ureteral Implantation, Lysis of Adhesions and Lymphadenectomy. There are no changes to the technological characteristics of the cleared *da Vinci Xi* Surgical System proposed in this submission. The *da Vinci Xi* Surgical System, Model IS4000 is a software-controlled, electro-mechanical system designed for surgeons to perform minimally invasive surgery. The Model IS4000 Surgical System consists of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and is used with an Endoscope, *EndoWrist* Instruments, and Accessories.

V. INDICATIONS FOR USE

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model lS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, 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, suturing, and

delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Precaution for Representative Uses

The demonstration of safety and effectiveness for the representative specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no changes to the technological characteristics of the cleared *da Vinci* Xi Surgical System (IS4000) proposed in this submission.

VII. PERFORMANCE DATA

Pre-Clinical Animal Study Data

Animal performance data were provided in this premarket notification, including the results from eight (8) evaluations in a total of 31 animals demonstrating use of *da Vinci Xi* Surgical System in the following procedures: Nephrectomy, Pyeloplasty, Hysterectomy and Salpingectomy/Oophorectomy (Adnexectomy), Nissen Fundoplication, Colectomy and Mitral Valve Repair. These data were previously submitted in support of clearance of the *da Vinci Xi* Surgical System, the *da Vinci Xi* Vessel Sealer, the *da Vinci Xi* Stapler 30 and the *da Vinci Xi* labeling modification to add specific procedures under the gynecologic laparoscopic surgical procedures general indication and the general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures general indication (K131861, K140189, K152241, K152578 and K153276) and also support inclusion of the additional representative, specific procedures.

Clinical Study Data

Published clinical data support use of the *da Vinci Xi* Surgical System for the representative, specific procedures that fall under the cleared "urologic laparoscopic surgical procedures" general Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the more complex/higher risk representative, specific procedures (referred to as "umbrella" procedures). The published data on these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedures

Published clinical data were provided for the following umbrella procedures: Prostatectomy (Radical), Nephrectomy (Partial, Radical), and Cystectomy (Radical). Sixty-one (61) publications were identified for these umbrella procedures based on specific search criteria and filters. These publications included

prospective randomized controlled trials, meta-analyses, systematic reviews, Health Technology Assessments (HTAs), large database studies and comparative studies. A detailed summary of the published clinical data on these procedures is provided in Tables 1-4 below.

The findings from the Prostatectomy (Radical) publications show that *da Vinci*-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates and EBL volumes; comparable or shorter lengths of hospital stay; comparable or lower intraoperative and postoperative complication rates; comparable rates of positive surgical margins; comparable or higher potency and continence rates; and, comparable or shorter operative times as compared to both open and laparoscopic surgical procedures. Several publications also noted increased operative times in the *da Vinci* procedures as compared to open procedures. However, this increase did not correlate with an increase in the reported mortality or complication rates. Additionally, these publications report comparable or lower conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures. One publication reported a higher intraoperative complication rate for *da Vinci*-assisted procedures as compared to open procedures[1]; one publication reported a higher postoperative complication rate for *da Vinci*-assisted procedures as compared to laparoscopic procedures[2]; and one publication reported a higher surgical margin rate for *da Vinci*-assisted procedures as compared to laparoscopic procedures.[3]

Outcomes reported in the Nephrectomy (Partial) publications demonstrate that *da Vinci*-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates and EBL volumes; comparable or shorter lengths of hospital stay; comparable or lower intraoperative and postoperative complication rates; comparable rates of positive surgical margins; comparable or shorter warm ischemia times; and, comparable or shorter operative times as compared to both open and laparoscopic surgical procedures. Several publications also noted increased operative times in the *da Vinci* procedures as compared to open procedures. However, this increase did not correlate with an increase in the reported mortality or complication rates. Additionally, these publications report comparable or lower conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures. Two publications reported higher warm ischemia times for *da Vinci*-assisted procedures as compared to open procedures.[4]

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[1] With regards to the higher intraoperative complication rate, the author notes, "Univariate analysis confirmed pre- and postoperative risk category, surgical technique and annual caseload to be significant contributors to intraoperative complication rate; however, only laparoscopic technique was significant on multivariate analysis [hazard ratio (HR) 2.45, 95% CI 1.65–3.62, $P < 0.001$]."

[2] The authors note, "We can say that once the learning curve is completed, LRP (laparoscopic radical prostatectomy) and RALP (robot-assisted radical prostatectomy) can be performed without a significant risk of major complications and with better results than RRP (retropubic radical prostatectomy)."

[3] The PSM rate was higher for the robotic cohort, however, the rates were similar (22.5% R vs. 22.2% L), and there was no difference in <=pT2 rates or >=pT3 rates, and no difference in biochemical recurrence (OR 1.15, p=0.9).

[4] The robotic cohort had a WIT of 18.9 minutes. Hadjipavlou, et al (B10) states: "The strongest surgical risk factor for CKD is ischaemia time; current data supports safe warm ischaemia time to be less than 20 minutes and cold ischaemia time up to 2 hours". The WIT reported for the robotic cohort was within the safe WIT of < 20 minutes. Xia, et al (B12) state: "Our primary analysis showed that OPN had the shorter WIT compared with RAPN. However, the sensitivity analysis showed no significant difference. Furthermore, there was no difference between the two groups regarding postoperative eGFR decline. Although WIT is an important predictor of postoperative renal function, it certainly is not the only factor. In experienced hands and appropriate patient selection, the WIT of RAPN can be controlled to less than 20 minutes. So the marginal difference of WIT between RAPN and OPN may not have much clinical significance for patients with adequate renal reserve."

The data provided in the Nephrectomy (Radical) publications show that *da Vinci*-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates; comparable EBL volumes; comparable or shorter lengths of hospital stay; and, comparable or lower intraoperative and postoperative complication rates; and, comparable or shorter operative times as compared to both open and/or laparoscopic surgical procedures. Additionally, these publications report comparable operative times and conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures. One publication reported a higher blood transfusion rate for *da Vinci*-assisted procedures as compared to open and laparoscopic procedures[5]; one publication reported a longer length of stay and a higher "any" complication rate for *da Vinci*-assisted procedures as compared to laparoscopic procedures.[6]

The findings from the Cystectomy (Radical) publications show that *da Vinci*-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates and EBL volumes; comparable or shorter lengths of hospital stay; comparable or lower intraoperative and postoperative complication rates; comparable rates of positive surgical margins; and, comparable operative times as compared to both open and laparoscopic surgical procedures. Several publications also noted increased operative times in the *da Vinci* procedures as compared to open and laparoscopic procedures. However, this increase did not correlate with an increase in the reported mortality or complication rates. One publication reported comparable conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures. One publication reported a higher post operative 90-day complication rate for *da Vinci*-assisted procedures as compared to open procedures.[7]

[5] The authors state, "The higher transfusion rate of nephrectomy with RALS (robotic assisted laparoscopic surgery) may be related to the relative infrequency of use compared with RALS for the other 3 procedures and to the overall nephrectomy volume, which may reflect a learning curve effect." (Note: this publication reported results from four (4) procedures: 1) Nephrectomy; 2) Radical Prostatectomy; 3) Partial Nephrectomy; and, 4) Pyeloplasty).

[6] The higher "any" complication rate for the robotic cohort was not associated with higher mortality or transfusion rates.

[7] The higher 90 day "any" complication rate reported in Leow for the *da Vinci* cohort did not result in a higher 90 day mortality rate; the mortality rate for the *da Vinci* cohort was significantly lower.

TABLE 1: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Prostatectomy (Radical)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (ml)	Length of Stay (days)	PostOp Complications (%)
A1. Pan (2014)	*da Vinci*	798	220.0 – 330.0	0.94 – 16.88%	Not Reported	1.4 / 5.8*
	Open	1571	151.0 – 289.0	1.99 – 65.0%		2.6 / 12.2*
A2. Trinh (2013)	*da Vinci*	11,889	Not Reported	1.95%	12.86%**	0.36 / 8.20
	Open	7389		7.74%	39.56%	0.99 / 11.14
A3. Davis (2013)	*da Vinci*	27,348	264.0	2.3%	2.2	10.6
	Open	30,124	204.0	11.5%	3.4	15.8
A4. Pilecki (2013)	*da Vinci*	4,374	212.3	1.87%	Not Reported	5.62
	Open	1,097	174.0	17.68%		23.2
A5. Ellimoottil (2014)	*da Vinci*	5,503	Not Reported	2.2%	19.4%^	2.1 / 16.6
	Open	3,605		11.2%	46.3%^	3.5 / 21.6
A6. Asimakopoulos (2011)	*da Vinci*	64	Not Reported	0%	Not Reported	8
	Lap	64		5%		15
A7. Porpiglia (2012)	*da Vinci*	60	147.6	202.0 ml	4.6	16.6
	Lap	60	138.1	234.1 ml	4.8	11.6
A8. Robertson (2013)	*da Vinci*	6,768	225	3.5%	Not Reported	0.5 – 3.9**
	Lap	4,952	239	5.0%		0.8 – 7.2**
A9. Novara (2012)	*da Vinci*	2,446/977	153.0 – 330.0	0 – 13.33%	1.9	1.89 – 41.67
	Open	2,843	127.0 – 289.0	1.67 – 80.65%	5.5 – 17.0	0.97 – 83.87
	Lap	903	159.5 – 267.0	0 – 48.57%	2.6 – 16.4	7.06 – 74.29
A10. Tewari (2012)	*da Vinci*	62,389	Not Reported	1.8%	1.4	7.8
	Open	167,184		16.5%	3.1	17.9
	Lap	57,303		4.7%	2.1	11.1
A11. DeCarlo (2014)	*da Vinci*	4,044	187.91	4.66%	5.87	18.52
	Open	7,047	179.03	19.93%	7.87	23.2
	Lap	2,841	236.54	6.3%	9.02	13.42
A12. Moran (2013)	*da Vinci*	1,581	160 – 341	0 – 20.0%	1.0 – 8.0	2.13 – 22.86
	Open	1,365	127.2 – 330	0 – 90.0%	1.3 – 17.0	4.79 – 40.0
	Lap	2,166	160.0 – 264.0	0 – 9.8%	1.76 – 6.1	6.34 – 9.02
A13. Yu (2012)	*da Vinci*	11,506	Not Reported	1.6%	1.7	8.4
	Open	9,694		5.2%	2.4	10.1
	Lap	611		≤ 1.8%	2.0	14.5
A14. Laird (2015)	*da Vinci*	424	Not Reported	0%	2.5	10.3
	Open	558		2.7%	4.7	8.8
	Lap	1181		0.4%	2.9	14.6
A15. Gandaglia (2014)	*da Vinci*	3476	Not Reported	1.9%	1	22.2
	Open	2439		8.9%	2	23.8
A16. Hyams (2013)	*da Vinci*	1499	Not Reported		1.7	Not Reported
	Open	2565			1.9	
A17. Kim (2013)	*da Vinci*	20,424	Not Reported		1	8.2
	Open	9413			2	11.3
A18. Lundstrom (2016)[##]	*da Vinci*	7256	Not Reported			0.07, 0.08, 0.06
	Open	9787				0.01, 0.02, 0
A19. Monn (2016)	*da Vinci*	9248	210	Not Reported	1	Not Reported
	Open	3206	162		2	
A20. Pearce (2016)	*da Vinci*	73,131	Not Reported		11.6%~	Not Reported
	Open	23,804			39.0%~	
A21. Seo (2016)	*da Vinci*	15,766	32 – 341	0 – 20.0	1 – 9	Not Reported
	Open	16,628	74 – 289	1.7 – 90	1 – 17	
A22. Yaxley (2016)	*da Vinci*	157	202.03	0.6	1.55	3.8
	Open	151	234.34	4.0	3.27	9.3
A23. Huang (2016)	*da Vinci*	4114	145.5 – 280.8	0 – 7.6	2.2 – 6.4	3.6 – 21.0
	Lap	5064	118.1 – 283.2	0 – 25.1	2.2 – 6.6	6.0 – 42.6
A24. Weiner (2015)	*da Vinci*	82,338	Not Reported			
	Lap	5077				
A25. Anderson (2012)	*da Vinci*	12,588	Not Reported		1.7 (vs. O), 1.9 (vs. L)	Not Reported
	Open	8968			2.5	
	Lap	547			1.8	
A26. Basto (2016)	*da Vinci*	233	Not Reported	0%	1.4	Not Reported
	Open	882		6%	3.6	
	Lap	233		15%	4.8	
A27. Stolzenburg (2016)	*da Vinci*	2495	Not Reported	2.6%	Not Reported	4.6
	Open	14,741		12.4%		5.4
	Lap	2831		3.8%		3.9

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (ml)	Length of Stay (days)	PostOp Complications (%)
A28. Sugihara (2014)^^	*da Vinci*	2126	322	Auto: 12.2% Homo: 0.7%	11	0.8
	Open	7202	268	Auto: 82.6% Homo: 7.3%	14	5.3
	Lap	2483	329	Auto: 41.8% Homo: 2.3%	11	3.9
A29. Wen (2014)	*da Vinci*	61,656	Not Reported		Odds Ratio 0.4[#]	Not Reported
	Open	111,361				

*Complication rates reported for: Bladder Neck Dissection / Inguinal Hernia; ^Percentage of cases with prolonged length of stay > 2 days reported; **Range includes complications reported for Clavien I – IV; ^^Sugihara reports anesthesia time and intraoperative and postoperative complications. [#]Wen, et al reports odds ratio only; [##] Rates reported for abdominal wall defects, wound dehiscence surgery and peritoneal drainage.; ~ Percentage of patients with LOS of 2 or more days

TABLE 2: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Nephrectomy (Partial)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (ml)	Length of Stay (days)	PostOp Complications (%)
B1. Aboumarzouk (2012)	*da Vinci*	313	152.17 – 233	122.4 – 368 ml	2.51 – 6.2	0 – 33.3
	Lap	404	117.5 – 226.05	136.7 – 580 ml	2.2 – 5.3	0 – 33.3
B2. Choi (2015)	*da Vinci*	1,152	140 – 376	93.3 – 368 ml	2 – 6.2	10.91 – 37.03* 2.67 – 11.11**
	Lap	1,088	156 – 293	100 – 400 ml	2 – 6.9	6.67 – 30.56* 0 – 15.56**
B3. Froghi (2013)	*da Vinci*	101	153.2 – 242	139.2 – 355.7 ml	2.8 – 6.2	8.53 – 18.52
	Lap	155	117.5 – 256	146.3 – 456.3 ml	2.95 – 5.3	0 – 20.34
B4. Mir (2011)	*da Vinci*	477	188	Not Reported	2.6	Not Reported
	Lap	2,220	200		3.2	
	Open	2,745	193		5.9	
B5. Zhang (2013)	*da Vinci*	425	151.17 – 233	122.40 – 323.00 ml	2.51 - 6.20	0 – 22.22
	Lap	341	117.50 – 226.50	146.30 – 387.50 ml	2.71 – 6.80	0 – 31.11
B6. Zhang (2014)	*da Vinci*	705	152 – 376	100 – 368 ml	2 – 6.2	0.78 – 26.63* 2.67 – 7.75**
	Lap	835	117.5 – 361	150 – 400 ml	2 – 14	2.54 - 30.56* 1.33 – 11.76**
B7. Wu (2014)	*da Vinci*	757	168 – 231.8	3.81 – 7.91%	2.5 – 6.2	9.52 – 40.66
	Open	2661	123 – 238.8	4.7 – 10.61%	4.5 – 18	13.79 – 54.21
B8. Ghani (2014)^	*da Vinci*	9095	Not Reported	5.8%	12.4%	22.1
	Lap	3508		7.1%	17.6%	24.9
	Open	25,461		10.6%	34.8%	30.5
B9. Kates (2015)	*da Vinci*	1078	Not Reported		2.51	Not Reported
	Lap	282			3.0	
B10. Hadjipavlou (2016)	*da Vinci*	83	179	272 mL	Not Reported	16.0
	Lap	192	159	322 mL		16.3
	Open	412	126	335 mL		18.5
B11. Leow (2016)	*da Vinci*	2671	108 – 376	88 – 490 ml	2.51 – 10.9	0 – 30.8
	Lap	2238	111 – 361	61 – 626 ml	2.0 – 14.0	4.8 – 27.8
B12. Xia (2016)	*da Vinci*	1216	122.3 – 263.0	0 – 14.5% / 57.5-322ml	1.51 – 9.67	0 – 25.5
	Open	2335	123.0 – 288.7	0 – 37.8% / 183.33-653.6ml	2.47 – 18.0	0 – 30.1

*Minor complications; **Major complications; ^Ghani reports prolonged length of stay.

TABLE 3: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Nephrectomy (Radical)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	PostOp Complications (%)
C1. Yu (2012)	*da Vinci*	327	Not Reported	23.5	5.2	29.9
	Lap	2,601		7.4	4.2	33.8
	Open	11,287		14.1	5.9	37.4
C2. Yang (2014)	*da Vinci*	7,787	Not Reported		3.0, IQR* 2-4	11.0
	Lap	16,525			3.0, IQR* 2-5	12.0
C3. Kates (2015)	*da Vinci*	376	Not Reported		3.52	4.0^
	Lap	1,098			4.0	4.0^
C4. Boger (2010)	*da Vinci*	13	168.0	Not Reported	2.0	15.4
	Lap	46	171.0		2.0	2.2
C5. Weinberg (2016)	*da Vinci*	5,849	Not Reported	4.5	2.12	27.8
	Lap	18,329		4.7	2.04	26.4
	Open	100,284		7.1	3.89	35.3
C6. Park (2012)	*da Vinci*	20	Not Reported		6	Not Reported
	Lap	20			7.4	
	Open	20			8	

*IQR = Interquartile Range; ^Readmission rates provided in study publication.

TABLE 4: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Cystectomy (Radical)

Publications		Study Size (N)	Operative Time (minutes)	Transfusions(%) or EBL (ml)	Length of Stay (days)	PostOp Complications (%)
D1. Ishii (2014)	*da Vinci*	461	252 – 455	2 – 40	Not Reported	25.0 – 66.34
	Open	287	211 – 393	19 – 50		25.0 – 61.54
D2. Li (2013)	*da Vinci*	364	252 – 606	2 – 52.63	4.4 – 40.2	33.33 – 66
	Open	598	210 – 420	24 – 71.43	5.3 – 37.0	50 – 73.33
D3. Novarra (2015)	*da Vinci*	565/ 62	308 – 638	4.17 – 57.14	8.0 - 40.2	15.38 – 83.33
	Open	943	259 – 507	24.0 – 86.96	8.0 – 37.0	16.67 – 78.57
	Lap	78	316 – 419	25.9 – 70.0	9.4 – 16	55.0 – 81.0
D4. Tang (2014)	*da Vinci*	382	252 – 638	0 – 53.85	5.0 – 40.2	15.38 – 66.0
	Open	510	211.2 – 507	30.30 – 86.96	6.0 – 27.0	16.67 – 85.00
D5. Xia (2015)	*da Vinci*	787	285.5 – 606	4.0 – 52.53	5.5 – 28.9	40.96 – 66
	Open	992	222 – 500.6	24.0 – 80.95	8 – 27.1	58.65 – 73.33
D6. Bochner (2014)	*da Vinci*	60	456	516 ml	8.0	62.0
	Open	58	329	676 ml	8.0	66.0
D7. Messer (2014)	*da Vinci*	20	300	40% / 400 ml	6.0	25.0
	Open	20	285.5	50% / 800 ml	6.0	25.0
D8. Fonseka (2015)	*da Vinci*	728	252 – 638	212 – 422 ml	5.1 – 40.2	28.0
	Lap	276	300 – 419	331 – 653 ml	9.13 – 16.1	72.1
	Open	1100	211 – 507	398 – 1790 ml	6 – 37.0	47.2
D9. Khan (2015)	*da Vinci*	20	389	585 ml	11.96	55
	Lap	19	301	460 ml	9.7	26
	Open	20	293	808 ml	14.4	70
D10. Bagi (2016)	*da Vinci*	348	Not Reported		8 – 15.5	Not Reported
	Open	1509			9 – 32	
D11. Hu (2016)	*da Vinci*	439	Not Reported	RR 0.97 (0.96 – 0.98)	10.1	Not Reported
	Open	7308			11.9	
D12. Leow (2014)	*da Vinci*	2667	386	Not Reported	10.2	Any 90d: 59.7
	Open	40,980	338		11.8	Any 90d: 56.8
D13.Mantulewicz (2016)	*da Vinci*	2397	Not Reported			
	Open	9639				
D14. Monn (2014)	*da Vinci*	3733	Not Reported		7	Any in-hospital: 33.2
	Open	25,986			8	Any in-hospital: 37.0

Covered Procedures

The published data on the above cited umbrella procedures were used to support clearance of the following covered procedures: Cystectomy (Partial), Donor Nephrectomy, Cyst Removal, Ureteral Implantation, Lysis of Adhesions and Lymphadenectomy.

VIII. CONCLUSION

Based on the information provided in this premarket notification, the inclusion of the following additional representative, specific procedures under the *da Vinci Xi* Surgical System "urologic surgical procedure" general indication is substantially equivalent to the predicate devices: Prostatectomy (Radical), Nephrectomy (Partial, Radical), and Cystectomy (Radical, Partial), Donor Nephrectomy, Cyst Removal, Ureteral Implantation, Lysis of Adhesions and Lymphadenectomy.