April 23, 2018

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

Re: K173842
Trade/Device Name: da Vinci Xi Surgical System (Model IS4000), and
da Vinci X Surgical System (Model IS4200)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 4, 2018
Received: April 5, 2018

Dear Cindy 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173842

Device Name
Intuitive Surgical® da Vinci® Xi Endoscopic Instrument Control System
(da Vinci Xi System, Model IS4000) and Endoscopic Instruments and Accessories

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi Surgical System Model IS4000) 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173842

Device Name
Intuitive Surgical® da Vinci® X Endoscopic Instrument Control System
(da Vinci X System, Model IS4200) and Endoscopic Instruments and Accessories

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci X Surgical System Model IS4200) 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.

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)

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K173842

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
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Date Summary Prepared: April 12, 2018

II. SUBJECT DEVICE INFORMATION

Device Trade Name: *da Vinci® Xi and X* Surgical Systems, Model IS4000 and Model IS4200
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 Xi and X* Surgical Systems, Models IS4000 and IS4200 (K131861, K152578, K153276, K161178, K170713, K171632, K171294)
Intuitive Surgical *da Vinci Si* 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 "general laparoscopic surgical procedures" Indication for Use of the *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294): Gastric Bypass (Roux-en-Y) and Gastric Sleeve. There are no changes to the technological characteristics of the cleared *da Vinci Xi or X* Surgical Systems (Models IS4000 and IS4200) proposed in this submission. The *da Vinci Xi and X* Surgical Systems, Models IS4000 and IS4200, are software-controlled, electro-mechanical systems designed for surgeons to perform minimally invasive surgery. The Model IS4000 and Model IS4200 Surgical Systems consist of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and are used with an Endoscope, *EndoWrist* Instruments, and Accessories.

V. INDICATIONS FOR USE

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Models: lS4000 and IS4200) 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 or *X* Surgical Systems (IS4000 and IS4200) proposed in this submission.

VII. PERFORMANCE DATA

Pre-Clinical Animal Study Data

This premarket notification is supported by animal study data including the results from six (6) evaluations in a total of 24 animals demonstrating use of *da Vinci Xi* Surgical System in the following procedures: Hysterectomy and Salpingectomy/Oophorectomy (Adnexectomy), Pyeloplasty, Nephrectomy, Nissen Fundoplication, Colectomy and Mitral Valve Repair. These data were initially submitted in support of clearance of the *da Vinci Xi* Surgical System (K131861) and were subsequently submitted in support of clearance the *da Vinci Xi* and *X* labeling modification to add specific procedures under the gynecologic laparoscopic surgical procedures Indications for Use (K152578); general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures Indications for Use (K153276); urologic surgical procedures Indications for Use (K161178); and, general laparoscopic surgical procedures Indications for Use (K170713 and K171632). These data also support inclusion of the subject representative, specific procedures.

Clinical Study Data

Published clinical data support use of the *da Vinci Xi and X* Surgical Systems (Models IS4000 and IS4200) in the subject representative, specific procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the most complex/highest risk representative, specific procedure of Gastric Bypass (Roux-en-Y) (referred to as the "umbrella" procedure). The published data on this "umbrella" procedure were deemed sufficient to cover the less complex/lower risk procedure (referred to as a "covered" procedure), so published clinical data on the covered procedure were not provided.

Umbrella Procedure

Published clinical data were provided for the umbrella procedure "Gastric Bypass (Roux-en-Y)". Ten (10) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included two (2) non-randomized, controlled, prospective studies (LOE 2b) and 8 retrospective cohort studies (LOE 3b) comparing *da Vinci*-assisted procedures with laparoscopic and/or open cohorts. A detailed summary of the published clinical data on this procedure is provided in **Table 1A** below.

The findings from the Gastric Bypass publications show that *da Vinci*-assisted procedures as compared to open procedures are associated with:

- Mortality: comparable mortality rates;
- Lengths of Hospital Stay: shorter lengths of hospital stay;
- Intraoperative Complication Rates: comparable intraoperative complication rates;
- Postoperative Complication Rates: comparable or lower postoperative complication rates;
- Anastomotic Leak Rate: comparable anastomotic leak rates;
- Anastomotic Stricture Rate: comparable anastomotic stricture rates;
- Reoperation Rate: comparable or lower reoperation rates[1]; and,
- Operative Time: Increased operative times were associated with *da Vinci* procedures. However, this increase was not associated with an increase in the mortality or complication rates.

The findings from the Gastric Bypass publications show that *da Vinci*-assisted procedures as compared to laparoscopic procedures are associated with:

- Mortality: comparable mortality rates;
- Estimated Blood Loss: comparable EBL volumes;
- Lengths of Hospital Stay: comparable or shorter lengths of hospital stay[2];
- Intraoperative Complication Rates: comparable intraoperative complication rates;

[1] No publications comparing *da Vinci*-assisted and open procedures reported readmission rates.

[2] One (1) publication (Benizri, *et al*) reported a longer length of stay, a higher reoperation rate and a higher 30-90 day anastomotic stricture rate for the robotic cohort. These outcomes were not associated with increased intraoperative, overall postoperative complication or mortality rates.

- Postoperative Complication Rates: comparable or lower postoperative complication rates;
- Anastomotic Leak Rate:
    - Comparable anastomotic leak rates when comparing hand-sewn gastrojejunal anastomoses in both cohorts;
    - Comparable or lower anastomotic leak rates when comparing stapled laparoscopic gastrojejunal anastomoses with hand-sewn robotic-assisted gastrojejunal anastomoses.
- Anastomotic Stricture Rate: [2];
    - Comparable anastomotic stricture rates when comparing hand-sewn gastrojejunal anastomoses in both cohorts;
    - Comparable or lower anastomotic stricture rates when comparing stapled laparoscopic gastrojejunal anastomoses with hand-sewn robotic-assisted gastrojejunal anastomoses.
- Reoperation Rate: comparable or lower reoperation rates[2];
- Readmission Rate: comparable readmission rates; and,
- Operative Time: comparable or shorter operative times (N = 3 publications). Increased operative times were associated with *da Vinci* procedures as compared laparoscopic procedures (N = 7 publications). However, this increase was not associated with an increase in the mortality or complication rates.
- Conversion Rates: comparable or lower conversion rates were reported for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

Covered Procedure

The published data on the Gastric Bypass (Roux-en-Y) umbrella procedure were used to support clearance of Gastric Sleeve procedures .

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* and *X* Surgical Systems (Models IS4000 and IS4200) “general laparoscopic surgical procedure” Indication for Use is substantially equivalent to the predicate devices: Gastric Bypass (Roux-en-Y) and Gastric Sleeve.

TABLE 1A: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Gastric Bypass (Roux-en-Y)

Author	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Conversion Rate (%)	Intraop Comp Rate	Postop Comp Rate	Mortality (in-hospital or 30 days)	Anastomotic Leak Rate (%)	Anastomotic Stricture Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
1. Ahmad 2015	Robotic	172	155.0	11.6	2.4	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0	NR
	Lap	173	135.3	13.4	2.5	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0	
2. Ayloo 2016	Robotic	61	213.1	24	2.8	3.3%	3.3	9.8%, 1.6%[a]	0.0%	0%[f]	NR	1.6	NR
	Lap	46	234.0	20.2	2.5	0.0%	0.0%	15.2%, 0%[a]	0.0%	2.2%[f]		2.2	
3. Benizri 2013	Robotic	100	130	NR	9.3	3.0%	21.0%[b]	24.0%[i]	1%	3	7%[g]	9	NR
	Lap	100	147		6.7	1.0%	16.0%$_b$	21.0%[i]	0%	0	0[g]	1	
4. Myers 2013	Robotic	100	144	NR	1.55	0.0%	NR	11.0%	0.0%	1.0%	6.0%	2.0	3.0
	Lap	100	87		2.17	0.0%		15.0%	0.0%	1.0%	2.0%	1.0	8.0
5. Smeenk 2016	Robotic	100	67	NR	2	0.0%	NR	5%, 17%[c]	0.0%	0.0%	0.0%	3.0	NR
	Lap	100	31		2	0.0%		5%, 13%[c]	0.0%	0.0%	1.0%	1.0	
6. Stefanidis 2017	Robotic	125	213	49	1.7	0.0%	0.0%	12.0%	0.0%	0	0.8%[h]	0.8	5.6
	Lap	121	155	56	2.1	0.8%	0.0%	20.0%	0.0%	0	2.4%[h]	6.6	8.2
7. Wood 2014	Robotic	100	182.29	NR	3.15	NR	NR	22%, 37%[d]	0.0%	0.0%	9%	0.0	8.0
	Lap	100	158.91		2.77			19%, 30%[d]	0.0%	0.0%	7%	0.0	7.0
8. Buchs 2016	Robotic	65	244	NR	6	3.1%	1.5%	13.8%	0.0%	0.0%	0.0%	3.1	NR
	Lap	54	238		16	13.0%	3.7%	27.8%	1.9%	3.7%	0.0%	13.0	
	Open	95	217		14	NA	1.1%	27.4%	1.1%	4.2%	1.1%	36.8	
9. Buchs 2014	Robotic	388	245.0	NR	6.2	0.8%	0.8%	11.6%	0.3%	0.3%	NR	1.0	NR
	Lap	389	215.8		10.4	4.9%	1.5%	16.7%	0.3%	3.6%		3.3	
10. Hagen 2012	Robotic	143	293	NR	7.4	1.4%	NR	16.1%	0.0%	0.0%	0.0%	0.7	NR
	Lap	323	206		11.0	5.0%		18.0%	0.0%	4.0%	6.8%	4.0	
	Open	524	NR		10.9	N/A		12.4%	0.6%	1.9%	1.1%	1.9	

a. Authors reported perioperative and long-term rates, respectively.
b. Authors reported “intraoperative difficulties”.
c. Authors reported 30 day and overall rates, respectively.
d. Authors reported surgical and all complications, respectively.
e. NR = Not Reported
f. Authors reported GI leak
g. Authors reported 30 – 90-day stricture rate
h. 1 year timepoint reported
i. 30-day rates reported