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

March 30, 2016

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

Re: K152578
Trade/Device Name: da Vinci Surgical System, Model IS4000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: March 21, 2016
Received: March 23, 2016

Dear Ms. 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.

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 -A

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)*
K152578

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 IS4000) 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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K152578

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: March 29, 2016

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)
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 "gynecologic laparoscopic surgical procedures" general indication for the *da Vinci Xi* Surgical System (K131861): Hysterectomy (Radical, Hysterectomy for Benign Disease[1]), Salpingectomy, Oophorectomy, Lymphadenectomy, Myomectomy, Sacrocolpopexy, Endometriosis Resection, Adnexectomy, Omentectomy, Parametrectomy, Cyst Removal, and Lysis of Adhesions. 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

[1] "Hysterectomy" was previously cleared as a representative, specific procedure for the *da Vinci Xi* Surgical System under K131861.

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.

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 7 evaluations in a total of 27 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 previously submitted in support of clearance of the *da Vinci Xi* Surgical System and the *da Vinci Xi* Vessel Sealer (K131861 and K140189) 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 "gynecologic 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: Hysterectomy (Radical) Salpingectomy, Oophorectomy, Lymphadenectomy, Myomectomy and Sacrocolpopexy. Twenty-one (21) publications were identified for these umbrella procedures based on specific search criteria and filters. These publications included randomized controlled trials, meta-analyses, systematic reviews or Health Technology Assessments and comparative studies. A detailed summary of the published clinical data on these procedures is provided in Tables 1-3 below.

The findings from the Hysterectomy, Salpingectomy, Oophorectomy and Lymphadenectomy publications show that *da Vinci*-assisted procedures are associated with comparable or fewer complications and blood transfusions and a shorter length of hospital stay as compared to both open and laparoscopic surgical procedures. These 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 complication rates. Additionally, these publications report comparable operative times and comparable or lower conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

Outcomes reported in the Myomectomy publications demonstrate that *da Vinci*-assisted procedures are associated with comparable complication rates; comparable or lower blood transfusion rates (Two publications reported a higher transfusion rate in the *da Vinci*-assisted cohorts as compared to the laparoscopic groups. However, Barakat noted that the cases completed with the laparoscopic approach were less challenging than those completed with *da Vinci* assistance and Gargiulo noted that the majority of transfusions in the *da Vinci-assisted* procedures were planned pre-operatively.); and comparable or shorter length of hospital stays as compared to both open and laparoscopic surgical procedures. These 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 complication rates. Additionally, these publications report comparable conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

The data provided in the Sacrocolpopexy publications show that *da Vinci*-assisted procedures are associated with comparable or lower complication rates; comparable blood transfusion rates and comparable or shorter length of hospital stays as compared to both open and laparoscopic surgical procedures. These 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 complication rates. Additionally, these publications reported comparable conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

TABLE 1: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Hysterectomy (Radical), Salpingectomy, Oophorectomy, Lymphadenectomy

Publications		Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	Complications (%)
1. Gaia(2010) *(Simple Total)*	*da Vinci*	207 – 219	1.7 - 2.6	1.2 - 1.4	2.0 - 3.8
	Open	130	7.2	3.9	14.5
	Lap	209	5.0	1.9	3.8
2a. Reza (2010) *(Simple Total)*	*da Vinci*	177 – 283	0 - 5	1.0 – 2.3	7.1 - 8.3
	Open	79 – 146.5	1.5 - 15	3.2 – 5.3	27.0
	Lap	171.1 – 255	2.5 - 10	1.2 – 2.0	13.0
2b. Reza (2010) *(Radical)*	*da Vinci*	144 - 290	0 – 7.5	1.0 – 3.7	13.9 - 30.4
	Open	114 – 247.8	8.2 – 35.7	3.2 – 5.6	19.4
	Lap	132 – 220.4	0	2.3 – 2.4	30.2
3. O'Sullivan (2011) *(Simple Total, Radical)*	*da Vinci*	173 - 231	6	1.5 - 1.9	18
	Open	181	27	4.4	36
	Lap	161	10	1.9	26
4a. O'Neill (2012) *(Simple Total)*	*da Vinci*	242	5	3.7	21
	Open	79 – 187.9	0 – 42.9	3.0 – 10.8	13.2 - 33.0
	Lap	82.9 – 287.0	0 - 16	1.2 – 7.7	2.5 – 21.9
4b. O'Neill (2012) *(Radical)*	*da Vinci*	202	4	1.7	11
	Open	114 - 283	8.2 – 42.5	2.8 – 9.5	4.7 – 70.8
	Lap	132 - 300	0	2.2 - 8.0	23.5 - 85.7
5. Ran (2015) *(Simple Total)*	*da Vinci*	96.7 - 331.8	1.0 – 3.8	1.0 – 7.9	8.4 – 13.2
	Open	79 - 187.9	10.0	4.0 – 10.8	35.6
	Lap	80 - 287	1.7	1.2 – 8.1	13.2
6. Geetha (2012) *(Radical)*	*da Vinci*	253.6	2.1	3.1	3.9~
	Open	219.7	25.2	8.4	18.2~
	Lap	259.7	5.3	5.6	6.6~
7. Shazly (2015) *(Radical)*	*da Vinci*	144 - 383	3.4 – 4.0	1.7 – 13.5	17.1 – 22.4
	Open	114 - 302.9	17.3	4.0 – 16.9	16.8
	Lap	132 - 364.2	6.6	2.0 – 10.0	20.2

TABLE 2: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Myomectomy

Publications		Operative Time (minutes)	Transfusions (%)	EBL (mL)	Length of Stay (days)	Complications (%)
8. Pundir (2013)	*da Vinci*	181 – 231.4	0 - 5	100 - 370	0.5 – 1.5	0 – 11.1
	Open	92.5 – 161.7	6.4 – 14.3	NA^^	3.0 – 3.6	0.3 – 13.0
	Lap	115 – 203	0 - 0.9	85.3 - 420	1.0 – 3.0	0.9 – 2.5
9. Barakat (2011)*	*da Vinci*		2.2	100		
	Lap		0	150		
10. Bedient (2009)*	*da Vinci*		4.8	100		
	Lap		5.0	250		
11. Gargiulo (2012)*	*da Vinci*		5.7	112.2		
	Lap		0.9	85.3		
12. Nezhat (2008)*	*da Vinci*		0	370		
	Lap		0	420		
13. Hsaio (2013)*	*da Vinci*		20	175		
	Lap		14	200		
14. Pluchino (2013)*	*da Vinci*		0	125.8		
	Lap		4.6	222.1		
15. Gobern (2013)*	*da Vinci*		6	100		
	Lap		12	100		
16. Gocmen (2013)*	*da Vinci*		Not Reported^	101.33		
	Lap			119.78		
17. Behera (2011)*	*da Vinci*		0	Not Reported		
	Lap		0			

TABLE 3: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Sacrocolpopexy

Publications		Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	Complications (%)
18. Serati (2014)	*da Vinci*	265	0.9	1.5	17.1
	Open	212	<1	3.0	27.6
	Lap	206	1.4	1.2	12.6
19. Paraiso (2011)	*da Vinci*	265	Not Reported	43 hours	Not Reported**
	Lap	199		34 hours	
20. Anger (2014)	*da Vinci*	202.8	Not Reported	Not Reported	15
	Lap	178.4			26
21. Flack (2015)	*da Vinci*	Not Reported	Not Reported	1.0	8.0
	Lap			2.0	7.0

~Rates reported are for "Infectious" complications; Non-infectious complication rates were 7.8%, 19.4% and 18.3% for the da Vinci-assisted, open and lap cohorts, respectively.

*Transfusion and/or EBL (estimated blood loss) data only were provided for this publication.

**Not Reported but publication states that there were no differences in intraoperative or post-operative complications.

^Transfusion rates not reported.

^^EBL volumes not provided. Author states "Pooled results showed that the mean EBL was significantly lower in the RLM group compared with the AM group."

Covered Procedures

The published data on the above cited umbrella procedures were used to support clearance of the following covered procedures: Endometriosis Resection, Adnexectomy, Omentectomy, Lysis of Adhesions, Cyst Removal and Parametrectomy.

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 "gynecologic laparoscopic surgical procedure" general indication is substantially equivalent to the predicate devices: Hysterectomy (Radical, Hysterectomy for Benign Disease[2]), Salpingectomy, Oophorectomy, Lymphadenectomy, Myomectomy, Sacrocolpopexy, Endometriosis Resection, Adnexectomy, Omentectomy, Parametrectomy, Cyst Removal, and Lysis of Adhesions.

The demonstration of safety and effectiveness was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to treatment of cancer (overall survival, disease-free survival, local recurrence).

[2] "Hysterectomy" was previously cleared as a representative, specific procedure for the *da Vinci Xi* Surgical System under K131861.