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

August 7, 2016

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

Re: K153276
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: July 15, 2016
Received: July 18, 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,

Christopher J. Ronk -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)*
K153276

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 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.

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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: August 1, 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, 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 "thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures" general indication for the *da Vinci Xi* Surgical System (K131861): Lobectomy, Mediastinal Mass Resection, Thymectomy, Segmentectomy, Wedge Resection 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 three (3) evaluations in a total of twenty (20) animals demonstrating use of *da Vinci Xi* Surgical System in Lung Resection and Lobectomy procedures. These data were also submitted in support of clearance of two (2) *Xi* EndoWrist Staplers (K140553 and K152421).

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 "thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures" 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: Lobectomy, Mediastinal Mass Resection and Thymectomy. Forty (40) publications were identified for these umbrella procedures based on specific search criteria and filters. These publications included retrospective, comparative and single arm studies. A detailed summary of the published clinical data on these procedures is provided in Tables 1-3 below.

The findings from the Lobectomy publications show that *da Vinci*-assisted procedures are associated with comparable or lower mortality rates; comparable complications; comparable or lower blood transfusion rates; and comparable or shorter lengths of hospital stay as compared to both open and VATS surgical procedures. Five (5) studies reported comparable or shorter operative times for *da Vinci*-

assisted procedures as compared to VATS procedures. Thirteen (13) publications noted increased operative times in the *da Vinci*-assisted procedures as compared to open and VATS procedures; however, this increase did not correlate with an increase in the reported mortality rates. Lastly, these publications report comparable or lower conversion rates for *da Vinci*-assisted procedures as compared to VATS procedures.

Outcomes reported in the Mediastinal Mass Resection comparative publications demonstrate that *da Vinci*-assisted procedures are associated with comparable mortality rates and operative times, comparable or lower complication rates and comparable or shorter lengths of hospital stay as compared to open surgical procedures. Data from five (5) publications reporting on single-arm studies using the *da Vinci* System for mediastinal mass resection procedures demonstrate that use of the *da Vinci* System can be accomplished with no reports of mortality and low complication rates. Intraoperative complications were < 1% in two (2) of the single-arm publications and post operative complication rates were ≤ 14% in all five (5) publications. Two (2) of the single-arm publications reported on conversion rates (0.65% and 4.3%) and three (3) publications reported low transfusion rates (0 – 1.4%). Operative times in the single-arm publications ranged from 85.9 minutes to 210.0 minutes and length of stay ranged from 1.0 to 12.8 days.

The data provided in the Thymectomy comparative publications show that *da Vinci*-assisted procedures are associated with comparable mortality rates; comparable or lower complication rates; comparable or shorter lengths of hospital stay; and comparable or lower transfusion rates/estimated blood loss as compared to both open and VATS surgical procedures. Operative times were comparable or longer in the *da Vinci*-assisted procedures as compared to open and VATS procedures, however, this increase did not correlate with higher mortality rates. Data from ten (10) publications reporting on single-arm studies using the *da Vinci* System for thymectomy procedures demonstrate that use of the *da Vinci* System in such procedures can be accomplished with no reports of mortality and low complication rates. No intraoperative complication rates were reported in eight (8) of the single-arm publications; two (2) of the publications reported intraoperative complication rates of 1.3% and 15.4%. Postoperative complication rates in the single-arm publications ranged from 3.6% - 15.4% and conversion rates ranged from 0% - 15.4%. Operative times in the single-arm publications ranged from 85.2 minutes to 155 minutes and length of stay ranged from 2.0 to 5.0 days.

TABLE 1: Comparison of *da Vinci* vs. Open and VATS Lobectomy

Publications		Sample Size (N)	Operative Time (minutes)~	Transfusions (%) and/or EBL (ml)	Length of Stay (days)~	Complications (%)
1. Cerfolio (2011)	*da Vinci*	106	132.0	30 ml	2.0	26.4
	Open	318	90.0	90 ml	4.0	37.8
2.Veronesi (2010)	*da Vinci*	54	236.0	0	5.0	20.4
	Open	54	154.0	6.0	6.0	20.4
3. Kent (2013)	*da Vinci*	430	NR	NR	4.0	44.4
	Open	20,238	NR	NR	6.0	55.1
	VATS	12,427	NR	NR	5.0	43.6
4. Oh (2013)	*da Vinci*	43	217.0	100 ml	4.0	28.0* / 2.0^
	Open	88	168.0	200 ml	10.0	24.0* /3.0^
5. Adams (2014)	*da Vinci*	120	241.5	0.9 / 0.9[#]	4.7	5.2** / 0.9^^
	Open	5,913	175.5	5.0 / 7.8[#]	7.3	10.8** / 1.1^^
	VATS	4,612	179.8	1.4 / 3.8[#]	5.3	8.9** / 1.0^^
6. Deen (2014)	*da Vinci*	57	223.0	NR	4.6	32.0
	Open	69	180.0	NR	5.5	30.0
	VATS	58	202.0	NR	4.8	31.0
7. Farivar (2014)	*da Vinci*	181	199.2	0 / 0[#]	3.2	6.1**
	Open	5,913	243.7	4.8 / 7.8[#]	7.3	10.7**
	VATS	4,612	239.0	1.3 /3.7[#]	5.3	8.9**
8. Augustin (2013)	*da Vinci*	26	215.0	NR	11.0	42.3
	VATS	26	183.0	NR	9.0	38.4
9. Bodner (2011)	*da Vinci*	26	228.0	NR	11.0	11.5
	VATS	114	183.0	NR	9.5	7.0
10. Jang (2011)	*da Vinci*	40	240.0	219.0 ml	6.0	10.0
	VATS	40	257.0	374.0 ml	9.0	32.5
11. B. Lee (2012)	*da Vinci*	100	209.0	NR	6.3	9.0
	VATS	100	157.0	NR	8.9	21.0
12. Louie (2012)	*da Vinci*	45	213.0	154.0 ml	4.0	43.5
	VATS	35	207.0	134.0 ml	4.5	35.3
13. B. Lee (2014)	*da Vinci*	35	161.0	0	3.0	11.0
	VATS	34	128.0	0	3.0	18.0
14. Swanson (2013)	*da Vinci*	295	269.4	NR	6.1	16.95[†] / 36.95[††]
	VATS	295	253.8	NR	5.8	18.98[†] / 38.31[††]
15. Paul (2014)	*da Vinci*	2,498	NR	NR	5.0	50.1~
	VATS	37,595	NR	NR	5.0	45.2~
16. Spillane (2014)	*da Vinci*	22	261.0	143 ml	4.4	9.0
	VATS	22	159.0	223 ml	5.5	22.0
17. B Lee (2015)	*da Vinci*	53	161.0	NR	3.0	11.0
	VATS	158	123.0	NR	3.0	24.0
18. Mahieu (2015)	*da Vinci*	28	190.0	100 ml	6.0	50.0
	VATS	28	185.0	200 ml	7.0	42.8

~Mean or median reported; *Air leak > 24 hours; ^Return to OR; [#]Intraoperative/Postoperative values; **Air leak > 5 days; ^^Bleeding requiring reoperation; [†]Major Complications; [††]Minor Complications;~Authors reported all complications which included Iatrogenic Complications (i.e., Intraoperative Complications)

TABLE 2: Comparison of *da Vinci* vs. Open and Single Arm Mediastinal Mass Resection Procedures

Publications		Sample Size (N)	Operative Time (minutes)*	Transfusions (%) and /or EBL (ml)	Length of Stay (days)*	Complications (%)
1. Balduyck (2011)	*da Vinci*	14	224.2	NR	9.6	21.4
	Open	22	243.8	NR	11.8	22.5
2. Seong (2014)	*da Vinci*	34	157.2	NR	2.7	0
	Open	34	139.3	NR	5.5	14.7
3. Cerfolio (2012)	*da Vinci*	75	95.0	NR	1.0	12.0
4. Huang (2014)	*da Vinci*	48	85.9	NR	3.9	2.0
5. Melfi (2012)	*da Vinci*	69	124.3	1.4	4.3	7.2
6. Nakamura (2014)	*da Vinci*	52	142.6 – 184.3	0	7.7 – 12.8	5.8
7. Seder (2013)	*da Vinci*	19	210.0	0	2.0	14.0

*Mean or median reported

TABLE 3: Comparison of *da Vinci* vs. Open and VATS and Single Arm Thymectomy Procedures

Publications		Sample Size (N)	Operative Time (minutes)*	Transfusions (%) and/or EBL (ml)	Length of Stay (days)*	Complications (%)
1. Weksler (2011)	*da Vinci*	15	130.0	41.67 ml	1.0	6.7
	Open	35	NR	151.43 ml	4.0	57.1
2. Ye (2014)	*da Vinci*	23	97.0	0% / 61.3 ml	3.7	4.3
	Open	51	214.5	0% / 466.1 ml	11.6	3.9
3. Renaud (2013)	*da Vinci*	6	189.2	<10 ml	5.0	0
	Open	15	55.0	24.6 ml	8.7	15.0
4. Ye (2013)	*da Vinci*	21	96.2	0% / 58.6 ml	3.7	4.8
	VATS	25	103.6	4.0% / 86.8 ml	6.7	4.0
5. Ruckert (2010)	*da Vinci*	75	187.0	NR	NR	2.7
	VATS	79	198.0	NR	NR	2.5
6. Jun (2014)	*da Vinci*	56	139.8	NR	7.18	10.7
	VATS	60	121.07	NR	7.23	6.66
7. Freeman (2011)	*da Vinci*	75	113.0	NR	2.2	5.3
8. Goldstein (2010)	*da Vinci*	26	127.0	NR	2.0	15.4
9. Huang (2013)	*da Vinci*	23	85.2	NR	3.6	4.3
10. Keijzers (2014)	*da Vinci*	125	123.0	NR	3.0	7.2
11. Marulli (2012)	*da Vinci*	79	155.0	1.2%	3.0	12.7
12. Marulli (2013)	*da Vinci*	100	120.0	3.0%	3.0	6.0
13. Mussi (2011)	*da Vinci*	14	139.0	NR	4.0	14.2
14. Rea (2011)	*da Vinci*	108	120.0	1.8%	3.0	3.6
15. Schneiter (2013)	*da Vinci*	20	NR	NR	5.0	10.0

*Mean or median reported

Covered Procedures

The published data on the above cited umbrella procedures were used to support clearance of the following covered procedures: Segmentectomy, Wedge Resection 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 "thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures" previously cleared Indications for Use is substantially equivalent to the predicate devices: Lobectomy, Mediastinal Mass Resection, Thymectomy, Segmentectomy, Wedge Resection and Lymphadenectomy.