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

June 13, 2017

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

Re: K170713
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: March 7, 2017
Received: March 9, 2017

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170713

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.

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

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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

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Date Summary Prepared: June 1, 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:

Following are the two predicate devices for this 510(k):

Intuitive Surgical *da Vinci* Surgical System, Model IS4000 (K131861, K152578, K153276, K161178), and 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 "Inguinal Hernia Repair" procedures under the cleared "general laparoscopic surgical procedures" indication for the *da Vinci Xi* Surgical System (K131861). 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

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 submitted in support of clearance of the *da Vinci Xi* Surgical System (K131861).

Clinical Study Data

A retrospective, multi-center, non-randomized controlled clinical study evaluating the use of the *da Vinci* Surgical System in Inguinal Hernia Repair procedures compared with open surgical procedures was conducted. This study included 652 and 602 subjects in the robotic-assisted and open cohorts, respectively, and was conducted at six (6) investigational sites in United States. Post operative data was collected throughout the thirty (30) day follow up period. Longer term endpoints such as inguinal hernia repair recurrence and chronic pain were not assessed in this study, and thus no claims regarding these clinical outcomes data should be inferred. The results demonstrated the safety and effectiveness of robotic-assisted inguinal hernia repair procedures. Additionally, such data provides information comparing the use of the *da Vinci* System in Inguinal Hernia Repair procedures with open surgery in the following key measures[1]:

- **Length of Stay**: comparable outpatient and inpatient lengths of hospital stay were reported for both the robotic-assisted and open cohorts. A statistically lower inpatient length of stay was found when propensity matched analysis was conducted.
- **Intraoperative Complications**: comparable intraoperative complication rates were reported for both the robotic-assisted and open cohorts.
- **Transfusions**: comparable blood transfusion rates were reported in both cohorts.
- **Postoperative Complications through Discharge**: comparable postoperative through discharge complication rates were reported for both the robotic-assisted and open cohorts.

[1] Propensity matched results are the same as the reported outcomes unless stated otherwise.

- **Postoperative Complications** (**Discharge through 30 days)** [2]: a lower rate of postoperative complications from discharge through 30 day follow up was reported for the robotic-assisted cohort as compared to the open cohort.
- **Readmission Rates**: comparable readmission rates were reported for both the robotic-assisted and open cohorts.
- **Reoperation Rates (Postoperative to Discharge)**: comparable reoperation rates were reported for the robotic-assisted cohort as compared to the open cohort.
- **Reoperation Rates (Discharge through 30 days)**: lower reoperation rates were reported for the robotic-assisted cohort as compared to the open cohort. This statistically lower rate of reoperations was not observed in the propensity matched analysis. The results of the propensity matched analysis showed comparable reoperation rates.
- **Mortality**: comparable mortality rates were reported in both cohorts.
- **Operative Time**: longer operative times were reported for the robotic-assisted cohort as compared to open surgery[3].

The data from both cohorts of the retrospective study are compared to data on laparoscopic procedures from eleven (11) publications referenced in Bittner, et al., "Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society", Chapter 4: "TEP versus TAPP: which is better?" *Surg Endosc* 29:289-321 (2015).

[2] Based on the results of the multivariate analysis, age greater than 65 years, presence of comorbidities and open inguinal hernia repair are associated with a higher likelihood of a postoperative complication within 30 days of surgery. Furthermore, propensity matched analyses showed that age greater than 65 years and open inguinal hernia are associated with a higher likelihood of a postoperative complication within 30 days of surgery.

[3] The longer operative time for the robotic-assisted cohort was not associated with increases in the complication, readmission, reoperation or mortality rates.

TABLE 1: *da Vinci,* Open and Laparoscopic Inguinal Hernia Repair

Outcome	Robotic-Assisted Cohort N=652[1]	Open Cohort N=602[1]	Laparoscopic Cohort N = 20 – N = 3,457[2]
Patient Demographics			
Mean age, y (± SD or range)	55.8 ± 15.6	57.2 ± 16.6	34.91 – 62.3
Female Gender, n (%)	64 (9.8)	60 (10.0)	0 – 6.1%
Male Gender, n (%)	588 (90.2)	542 (90.0)	88 – 100%
Mean BMI, kg/ m^2 (± SD or range)	27.3 ± 5.1	26.7 ± 5.0	22.4 – 26.8
Length of Stay			
Inpatient (days)	3.01 ± 4.65 (n=52)	4.86[6] ± 5.35 (n=51)	0.8 - 5 days
Outpatient (hours)	7.16 ± 3.01	6.89 ± 2.77	
Intraoperative Complications, n (%)	2 (0.3)	0	0 – 8%
Transfusions, n (%)			
Intraoperative	0	0	Not Reported
Perioperative	2 (0.3)	2 (0.3)	
Postoperative Complications, n (%)			
Postop to discharge	15 (2.3)	10 (1.7)	0 – 36%[2a]
Post discharge to 30 days	28 (4.3)	44 (7.3)[7]	
Readmission Rates, n (%)*	23 (3.5)	26 (4.3)[9]	Not Reported
Reoperation Rates			
Postop to discharge	3 (0.5)*	2 (0.3)*	0 – 2.5%[2a]
Post discharge to 30 days	0*	8 (1.3)*[8]	
Mortality, n	0	1	0
Operative Time, min (± SD or range)	79.7 ± 31.7	45.0 ± 21.7	32.6 – 110
Adverse Events, n[3]	44	49[10]	Not Applicable
All Complications, n (%)[4]	45 (6.9)	51 (8.5)[11]	7.9 – 8.7%
Conversion Rate, n (%)	6 (0.9)	Not Applicable	0 – 4%

*Related to Inguinal Hernia Repair Procedure

[1]Data from a retrospective, multi-center, non-randomized controlled clinical study evaluating the use of the *da Vinci* Surgical System in Inguinal Hernia Repair procedures compared with open surgical procedures. This table includes all subjects with complete data (missing data is omitted), despite propensity scores showing that one third of investigational subjects did not have an appropriate match among control subjects and large site to site differences.

[2]Data from eleven (11) publications referenced in Bittner, et al., "Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society", Chapter 4: "TEP versus TAPP: which is better?" *Surg Endosc* 29:289-321 (2015).

[2a]Post operative complications and reoperation rates were not segregated by specific timeframes. [Note: One publication (Bracale, et al (2012) reported only relative risk and mean differences for post operative complications and operative time / length of stay.]

[3]Adverse Events defined as death or serious injury (i.e., Clavien Grade IIIa or higher). Publications cited in Bittner, et al. did not categorize complications/events by severity (i.e., serious).

[4]All complications defined as all intraoperative and postoperative complications for the robotic-assisted and open cohorts. In the laparoscopic cohort, one publication cited in Bittner, et al reported "overall morbidity".

[5]Inguinal hernia recurrence and chronic pain were not assessed in this study.

[6] The results are heavily influenced by one site. See also other footnotes below. Without this site, the mean number of inpatient days for open procedures is 3.00.

[7]28/44 complications came from one of the 6 sites.

[8] Of the 10 reoperations, 80% (8/10)were done at one site.

[9]14/26 readmissions were at one site

[10] 30/49 AEs occurred at one site

[11] 30/51 were reported at one site.

VIII. CONCLUSION

Based on the information provided in this premarket notification, the inclusion "Inguinal Hernia Repair" procedures under the *da Vinci Xi* Surgical System "general laparoscopic surgical procedure" indication is substantially equivalent to the predicate devices. The basis of this substantial equivalence determination was an assessment of the immediate post-operative outcomes comparing the robotic-assisted surgery inguinal hernia repair versus laparoscopic surgery inguinal hernia repair.