July 19, 2018

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

Re: K173585
Trade/Device Name: da Vinci Xi Surgical System (Model IS4000),
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: June 18, 2018
Received: June 19, 2018

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.

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 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)*

K173585

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.

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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)*

K173585

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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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)
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Date Summary Prepared: July 19, 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, K171294, K171632)
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 "Ventral Hernia Repair" (VHR) procedures under the cleared "general laparoscopic surgical procedures" Indication for Use of the *da Vinci Xi* Surgical System, Model IS4000 and the *da Vinci X* Surgical System, Model IS4200. 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

da Vinci Xi Surgical System

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci Xi* 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.

da Vinci X Surgical System

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.

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).

Real World Evidence from the AHSQC Registry Database

Real world evidence (RWE) from the AHSQC registry database support use of the *da Vinci Xi and X* Surgical Systems (Models IS4000 and IS4200) in "Ventral Hernia Repair" (VHR) procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. The RWE provided included propensity matched comparative data from robotic-assisted, open and laparoscopic cohorts in non-complex VHR procedures. Non-complex VHR procedures were defined as ventral (e.g., incisional, epigastric, umbilical) hernia repairs without myofascial release. Additionally, propensity matched comparative data from robotic-assisted and open cohorts and unmatched comparative data from robotic-assisted and laparoscopic cohorts in complex VHR procedures were also included. Complex VHR procedures were defined as incisional hernia repair plus myofascial release. Longer term endpoints beyond 30 days, such as ventral hernia repair recurrence and chronic pain were not assessed in this analysis, and thus no claims regarding these clinical outcomes data should be inferred. The results demonstrated the safety and effectiveness of robotic-assisted ventral hernia repair procedures.

Non-Complex VHR Procedures: Robotic-Assisted v. Open Surgery

Table 1 summarizes the results of the RWE that compared the results of non-complex robotic-assisted and open VHR procedures. The RWE included information comparing the use of the *da Vinci* System in non-complex Ventral Hernia Repair procedures with open surgery in the following key measures:

- **Length of Stay**: comparable lengths of hospital stay were reported for both the robotic-assisted and open cohorts.
- **Intraoperative Complications**: comparable intraoperative complication rates were reported for both the robotic-assisted and open cohorts.
- **Transfusions**: comparable intraoperative and postoperative blood transfusion rates were reported in both the robotic-assisted and open cohorts.
- **Postoperative Complications through 30 days**: comparable postoperative complications through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- **Readmission Rates through 30 days**: comparable readmission rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- **Re-encounter Rates through 30 days**: a lower clinic re-encounter rate through 30 days follow up was reported for the robotic-assisted cohort (29%) as compared to the open cohort (41%). Comparable emergency room re-encounter rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- **Reoperation Rates through 30 days**: comparable reoperation rates were reported for both the robotic-assisted and open cohorts.
- **Recurrence Rates through 30 days**: comparable surgeon reported recurrence rates were reported for both the robotic-assisted and open cohorts through the 30-day postoperative period.
- **Mortality through 30 days**: comparable mortality rates were reported in both the robotic-assisted and open cohorts through the 30-day postoperative period.

- **Operative Time**: longer operative times were reported for the robotic-assisted cohort as compared to the open cohort[1].

TABLE 1: Propensity Score Matched *da Vinci* and Open Non-Complex Ventral Hernia Repair (without myofascial release)^

Outcome	Robotic-Assisted Cohort (N=871)	Open Cohort (N=871)
Patient Demographics		
Mean age, y (± SD)	56 ± 14	55 ± 14
Female Gender, n (%)	399 (46)	361 (41)
Male Gender, n (%)	472 (54)	510 (59)
Mean BMI, kg/ m^2 (± SD)	33 ± 7	32 ± 7
Length of Stay (days), mean ± SD	2 ± 7	2 ± 14
Intraoperative Complications, n (%)	11 (1)	5 (1)
Transfusions, n (%)		
Intraoperative	1 (< 1)	0 (0)
Postoperative	0 (0)	2 (< 1)
Postoperative Complications, n (%)*	64 (9)	75 (11)
Readmission Rates, n (%)*	14 (2)	21 (3)
Reoperation Rates, n (%)*	3 (< 1)	8 (1)
Re-encounter Rates, n (%)*		
Clinic	207 (29)	291 (41)
Emergency Room	31 (4)	20 (3)
Mortality, n (%)*	1 (< 1)	0 (0)
Operative Time, minutes, n (%)		
0 – 59	111 (13)	432 (50)
60 – 119	396 (45)	304 (35)
120 – 179	247 (28)	86 (10)
180 – 239	81 (9)	28 (3)
240+	36 (4)	21 (2)
Conversion Rate, n (%)	5 (1)	Not Applicable
Recurrence Rate, n (%)*	5 (1)	0 (0)

* Through 30 days post-operatively

^ Includes data from the AHSQC registry for procedures that occurred between July 7, 2013 and January 1, 2017. The total number of non-complex VHR procedures in the registry during this time period was 873 and 3,979 for the robotic-assisted and open cohorts, respectively. The total number in the propensity matched cohorts is 871 as noted in the column header of the above table.

Non-Complex VHR Procedures: Robotic-Assisted v. Laparoscopic Surgery

Table 2 summarizes the results of the RWE that compared the results of non-complex robotic-assisted and open VHR procedures. The RWE included information comparing the use of the *da Vinci* System in non-complex Ventral Hernia Repair procedures with laparoscopic surgery in the following key measures:

- **Length of Stay**: a shorter length of hospital stay was reported for the robotic-assisted cohort (2 days ± 7) as compared to the laparoscopic cohort (4 days ± 13).
- **Intraoperative Complications**: comparable intraoperative complication rates were reported for both the robotic-assisted and laparoscopic cohorts.
- **Transfusions**: comparable intraoperative and postoperative blood transfusion rates were reported in both the robotic-assisted and laparoscopic cohorts.

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

- **Conversion Rate**: a comparable conversion rate was reported for the robotic-assisted cohort as compared to the laparoscopic cohort.
- **Postoperative Complications through 30 days**: comparable postoperative complications through 30 days follow up were reported for both the robotic-assisted and laparoscopic cohorts.
- **Readmission Rates through 30 days**: comparable readmission rates through 30 days follow up were reported for both the robotic-assisted and laparoscopic cohorts.
- **Re-encounter Rates through 30 days**: comparable clinic and emergency room re-encounter rates through 30 days follow up were reported for the robotic-assisted cohort as compared to the laparoscopic cohort.
- **Reoperation Rates through 30 days**: comparable reoperation rates were reported for both the robotic-assisted and laparoscopic cohorts.
- **Recurrence Rates through 30 days**: comparable surgeon reported recurrence rates were reported for both the robotic-assisted and laparoscopic cohorts through the 30-day postoperative period.
- **Mortality through 30 days**: comparable mortality rates were reported in both the robotic-assisted and laparoscopic cohorts through the 30-day postoperative period.
- **Operative Time**: longer operative times were reported for the robotic-assisted cohort as compared to the laparoscopic cohort[2].

TABLE 2: Propensity Score Matched *da Vinci* and Laparoscopic Non-Complex Ventral Hernia Repair (without myofascial release)^

Outcome	Robotic-Assisted Cohort (N=615)	Laparoscopic Cohort (N=615)
Patient Demographics		
Mean age, y (± SD)	55 ± 14	56 ± 14
Female Gender, n (%)	305 (50)	284 (46)
Male Gender, n (%)	310 (50)	331 (54)
Mean BMI, kg/ m^2 (± SD)	33 ± 7	33 ± 8
Length of Stay (days), mean ± SD	2 ± 7	4 ± 13
Intraoperative Complications, n (%)	6 (1)	8 (1)
Transfusions, n (%)		
Intraoperative	1 (< 1)	0 (0)
Postoperative	0 (0)	1 (< 1)
Postoperative Complications, n (%)*	55 (10)	59 (11)
Readmission Rates, n (%)*	8 (2)	17 (3)
Reoperation Rates*, n (%)	1 (< 1)	5 (1)
Re-encounter Rates*, (%)		
Clinic	153 (29)	181 (35)
Emergency Room	21 (4)	18 (4)
Mortality, n (%)*	1 (< 1)	0 (0)
Operative Time, minutes, n (%)		
0 – 59	86 (14)	175 (28)
60 – 119	265 (43)	308 (50)
120 – 179	175 (28)	103 (17)
180 – 239	60 (10)	21 (3)
240+	29 (5)	8 (1)
Conversion Rate, n (%)	3 (< 1)	14 (2)
Recurrence Rate, n (%)	4 (1)	4 (1)

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

* Through 30 days post-operatively

^ Includes data from the AHSQC registry for procedures that occurred between July 7, 2013 and January 1, 2017. The total number of non-complex VHR procedures in the registry during this time period was 873 and 1,961 for the robotic-assisted and laparoscopic cohorts, respectively. The total number in the propensity matched cohorts is 615 as noted in the column header of the above table.

Complex VHR Procedures: Robotic-Assisted v. Open Surgery

Table 3 summarizes the results of the RWE that compared the results of complex robotic-assisted and open VHR procedures. The RWE included information comparing the use of the *da Vinci* System in complex Ventral Hernia Repair procedures with open surgery in the following key measures:

- **Length of Stay**: a shorter length of hospital stay was reported in the robotic-assisted cohort (2 days ± 3) as compared to the open cohort (5 days ± 7).
- **Intraoperative Complications**: comparable intraoperative complication rates were reported for both the robotic-assisted and open cohorts.
- **Transfusions**: comparable intraoperative and postoperative blood transfusion rates were reported in both the robotic-assisted and open cohorts.
- **Postoperative Complications through 30 days**: comparable postoperative complication rates through 30 days follow up were reported for both the robotic-assisted cohort and open cohort.
- **Readmission Rates through 30 days**: comparable readmission rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- **Re-encounter Rates through 30 days**: a lower clinic re-encounter rate through 30 days follow up was reported for the robotic-assisted cohort (16%) as compared to the open cohort (27%). Comparable emergency room re-encounter rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- **Reoperation Rates through 30 days**: comparable reoperation rates were reported for both the robotic-assisted cohort and open cohorts.
- **Recurrence Rates through 30 days**: comparable surgeon reported recurrence rates were reported for both the robotic-assisted and open cohorts through the 30-day postoperative period.
- **Mortality through 30 days**: comparable mortality rates were reported in both the robotic-assisted and open cohorts through the 30-day postoperative period.
- **Operative Time**: longer operative times were reported for the robotic-assisted cohort as compared to the open cohort[3].

TABLE 3: Propensity Score Matched *da Vinci* and Open Complex Ventral Hernia Repair (with myofascial release)^

Outcome	Robotic-Assisted Cohort (N=297)	Open Cohort (N=297)
Patient Demographics		
Mean age, y (± SD)	57 ± 13	57 ± 13
Female Gender, n (%)	169 (57)	159 (54)
Male Gender, n (%)	128 (43)	138 (46)
Mean BMI, kg/ m^2 (± SD)	33 ± 7	33 ± 7
Length of Stay (days), mean ± SD	2 ± 3	5 ± 7
Intraoperative Complications, n (%)	7 (2)	9 (3)

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

Outcome	Robotic-Assisted Cohort (N=297)	Open Cohort (N=297)
Transfusions, n (%)		
Intraoperative	0 (0)	0 (0)
Postoperative	0 (0)	1 (< 1)
Postoperative Complications, n (%)*	66 (24)	54 (20)
Readmission Rates, n (%)*	19 (7)	12 (4)
Reoperation Rates, n (%)*	8 (3)	4 (1)
Re-encounter Rates, n (%)*		
Clinic	44 (16)	74 (27)
Emergency Room	14 (5)	12 (4)
Mortality, n (%)*	1 (< 1)	0 (0)
Operative Time, minutes, n (%)		
0 – 59	0 (0)	8 (3)
60 – 119	12 (4)	84 (28)
120 – 179	53 (18)	106 (36)
180 – 239	98 (33)	48 (16)
240+	134 (45)	51 (17)
Conversion Rate, n (%)	12 (4)	Not Applicable
Recurrence Rate, n (%)*	4 (1)	2 (1)

* Through 30 days post-operatively

^ Includes data from the AHSQC registry for procedures that occurred between July 7, 2013 and January 1, 2017. The total number of complex VHR procedures in the registry during this time period was 305 and 3,106 for the robotic-assisted and open cohorts, respectively. The total number in the propensity matched cohorts is 297 as noted in the column header of the above table.

Complex VHR Procedures: Robotic-Assisted v. Laparoscopic Surgery

Table 4a provides a summary of the results of the RWE that compared the results of complex robotic-assisted and laparoscopic VHR procedures and a summary of the published literature on complex laparoscopic VHR procedures. The limited sample size of the complex laparoscopic cohort in the AHSQC Registry Database precluded matching and a comparative analysis between these cohorts in the AHSQC Registry Database. **Table 4b** includes the detailed data from nine (9) publications reporting on complex laparoscopic VHR procedures. These publications were selected based on specific search criteria and filters and included 6 comparative studies (LOE 2 & 3b) and 3 single-arm studies (LOE 5). The results from the literature were not matched with the available robotic-assisted data from the AHSQC Registry Database and no comparative analysis was conducted. Clinical analysis of the *da Vinci* Surgical Systems in robotically-assisted complex ventral hernia repair procedures raises no new issues of safety or effectiveness for the proposed labeling modification and therefore is substantially equivalent.

TABLE 4a: Unmatched *da Vinci* and Laparoscopic Complex Ventral Hernia Repair from the AHSQC Registry Database (with myofascial release)**

Outcome	Robotic-Assisted Cohort (N=305)	AHSQC Laparoscopic Cohort (N=27)	Summary of Table 4b Published Literature Laparoscopic Cohort (N = 3 – 53)
Patient Demographics			
Mean age, y (± SD)	57 ± 13	58 ± 12	48.6 – 70 years
Female Gender, n (%)	175 (57)	14 (52)	20 – 68%
Male Gender, n (%)	130 (43)	13 (48)	32 – 80%
Mean BMI, kg/ m^2 (± SD)	33 ± 7	34 ± 7	29.71 – 36 kg/ m^2
Length of Stay (days), mean ± SD	2 ± 3	4 ± 3	1 – 9.2 days
Intraoperative Complications, n (%)	7 (2)	3 (11)	0 – 1.5%

Outcome	Robotic-Assisted Cohort (N=305)	AHSQC Laparoscopic Cohort (N=27)	Summary of Table 4b Published Literature Laparoscopic Cohort (N = 3 – 53)
Transfusions, n (%) Intraoperative Postoperative	 0 (0) 0 (0)	 0 (0) 0 (0)	Transfusions: 0 Estimated Blood Loss: 51 – 91.7 ml
Postoperative Complications, n (%)*	66 (24)	3 (11)	0 – 60%
Readmission Rates, n (%)*	19 (7)	2 (7)	0 – 13%
Reoperation Rates, n (%)*	8 (3)	0 (0)	0 – 20%
Re-encounter Rates, n (%)* Clinic Emergency Room	 48 (17) 14 (5)	 6 (22) 4 (15)	0
Mortality, n (%)*	1 (< 1)	0 (0)	0 – 1.9%
Operative Time, minutes, n (%) 0 – 59 60 – 119 120 – 179 180 – 239 240+	 0 (0) 12 (4) 54 (18) 100 (33) 139 (46)	 0 (0) 3 (11) 8 (30) 11 (41) 5 (19)	125 – 372 minutes
Conversion Rate, n (%)	12 (4)	19 (70)	0
Recurrence Rate, n (%)*	4 (1)	0 (0)	Not Reported

* Through 30 days post-operatively

** The data presented in this table are not propensity score matched and include the results for all complex VHR cases in the AHSQC registry during the access dates between July 7, 2013 and January 1, 2017 for both the robotic-assisted and laparoscopic cohorts.

TABLE 4b: Published Literature Results - Laparoscopic Complex Ventral Hernia Repair (with myofascial release)

Author/Year	Lap/Endoscopic Study Size (N)	Mean Age, y (±SD)	Gender (M/F)	Mean BMI, kg/m^2 (SD)	Mean Operation Time (minutes) (SD)	EBL (ml) or Tranfusions	Length of Stay, days (SD)	Conversion Rate (%)	Intraoperative Complication Rate (%)	Postoperative Complication Rate (%)	Mortality (in-hospital or 30 days)	Reoperation Rate (30d)	Re-encounter Rate (30d)	Readmission Rate (30 d)	Recurrence Rate (30d)
Azoury 2014	25	59 (11)	32% / 68%	35.4 (8)	278 (73)	63 (29)	4 (2)	NR	NR	20% (Wound complications)	0.0%	NR	NR	NR	NR
Belyanksy 2016	3	70	66.7% / 33.3%	30.1	329 (OR time)	91.7	4.7	0.0%	0.0%	33% (1/3 subjects, prolonged ileus prior to discharge)	0.0%	0.0%	0.0%	0.0%	NR
Belyanksy 2017	38	NR Not stratified by cohort			NR	NR	NR	NR	NR	2.6% (1/38)	0%	0 (90d)	NR (likely 0 from inference)	0 (90d)	NR
Daes 2014	5	NR Not stratified by cohort			NR	NR	1	NR	0	0.0%	0.0%	0.0%	0.0%	0.0%	NR
Giurgius 2012	21	51 (13)	48% / 52%	36 (7)	229 (57)	NR	6.3 (3.6)	NR	NR	19.0%	NR	NR	NR	NR	NR
Moazzez 2013	5	48.6 (7.9)	80%/20%	29.71 (3.4)	372 (104)	0 transfusions (No significant bleeding reported)	9.2 (5.4)	0.0%	0.0%	60% (3/5) subjects with acute (<30d)/in-hospital complications	0.0%	20% (1/5)	NR	NR	NR for 30 day (60% with median of 12.6m)
Muse 2018	53	54.4	40%/60%	35.3	224	NR	5	NR	NR	13% (Wound complications)	1.9% (Timeframe NR)	NR	NR	13%	NR for 30 day (15% overall)
Parker 2011	8	64.4	1.7:1 (reported as ratio)	30.5	226.8	51 mL 0 units transfused	5.4	NR	NR	0% (Wound complications, timeframe NR)	1.9%	NR	NR	0%	NR
Schroeder 2013	43 (27 incisional)	57	62.8% / 37.2%	NR	125	NR	3.4	NR	1.5%	7.0%	NR	NR	NR	NR	NR for 30 d (0 overall through f/u)

NR = Not Reported

VIII. CONCLUSION

Based on the information provided in this premarket notification, the inclusion of "Ventral Hernia Repair" procedures under the *da Vinci Xi* and *X* Surgical Systems (Models IS4000 and IS4200) previously cleared "general laparoscopic surgical procedure" Indication for Use is substantially equivalent to the predicate devices. The basis of this substantial equivalence determination was an assessment of the immediate post-operative outcomes through 30 days comparing the robotic-assisted surgery ventral hernia repair versus laparoscopic ventral hernia repair.