November 22, 2022

Intuitive Surgical, Inc
Connor McCarty
Senior Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K223080
Trade/Device Name: da Vinci X Surgical System (IS4200), da Vinci Xi Surgical System (IS4000)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: September 30, 2022
Received: September 30, 2022

Dear Connor McCarty:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2022.11.22 13:42:23 -05'00'

Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223080

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 lntuitive 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. Itis 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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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:

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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223080

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 lntuitive 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. Itis 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.

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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: Connor McCarty
Senior Regulatory Engineer
Connor.McCarty@intusurg.com
805.798.4205

Date Summary Prepared: September 30, 2022

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 Devices: Intuitive Surgical *da Vinci Xi and X* Surgical Systems, Models IS4000 and IS4200 (K131861, K152578, K153276, K161178, K170713, K171632, K171294 K172643, K173842, K173585, K182140, K183086, K202834, K211784)
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 "duodenal switch bariatric surgical procedures" under the cleared "general laparoscopic surgical procedures" Indications for Use of the *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294):

1. Biliopancreatic Diversion-Duodenal-Switch/BPD-DS,
2. Single Anastomosis-Duodeno Ileal Bypass with Sleeve/SADI-S,
3. One Anastomosis Duodenal Switch/OADS, and
4. Transit Bipartition/TB.

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 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 INTENDED USE, INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no changes to the technological characteristics for the subject devices compared to the cleared predicate devices, *da Vinci Xi* Surgical System, Model IS4000 (K131861) and the *da Vinci X* Surgical System, Model IS4200 (K171294). This 510(k) is for a labeling modification to include the representative, specific "duodenal switch bariatric surgical procedures" as a labeled use under the cleared "general laparoscopic surgical procedures" Indications for Use of the cleared predicate devices, *da Vinci Xi* Surgical System, Model IS4000 and the *da Vinci X* Surgical System, Model IS4200. The subject devices differ from the predicate devices by this modification to the labeling. Results of clinical data from the literature demonstrated that the subject devices have the same intended use as the predicate devices.

VII. PERFORMANCE DATA

There were no technological changes to the subject devices, thus no bench testing, electromagnetic compatibility testing, sterilization testing or biocompatibility testing was required.

Real World Evidence (RWE) from the Premier Health Database (PHD)

Real world evidence (RWE) from the Premier Health Database (PHD) support use of the *da Vinci Xi* and *X* Surgical Systems (Models IS4000 and IS4200) in "duodenal switch bariatric surgical procedures" that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Real-world data (RWD) were not provided for all of the representative, specific procedures. Instead, RWD were provided only for the most complex/highest risk representative, duodenal switch bariatric surgical procedures (referred to as the "umbrella" procedures). The RWE for these "umbrella" procedures (i.e.,

Biliopancreatic Diversion-Duodenal-Switch/BPD-DS, Single Anastomosis-Duodeno Ileal Bypass with Sleeve/SADI-S, and, One Anastomosis Duodenal Switch/OADS) were deemed sufficient to cover the less complex/lower risk procedure of "Transit Bipartition" (referred to as "covered" procedure), so RWD on the noted covered procedure was not provided.

Using ICD-10 and CPT codes, 1,878 patients, including 377 robotic-assisted and 1501 laparoscopic, were identified in PHD that underwent primary DS Bariatric surgical procedures for an obesity indication at 73 hospitals in the USA from 2016 to 2020. After propensity score matching, 314 patients were evaluated in each cohort. **Table 1** includes a summary of the unmatched and propensity matched comparative data from the robotic-assisted and laparoscopic duodenal switch bariatric surgical procedure cohorts. Outcomes were assessed through 30 days. The results demonstrated the safety and effectiveness of robotic-assisted duodenal switch bariatric surgical procedures. The findings from this analysis demonstrate that *da Vinci*-assisted procedures as compared to laparoscopic procedures are substantially equivalent based on the following nine (9) outcomes of interest:

1. Operative Times
2. Lengths of Hospital Stay (LOS)
3. Conversion Rates
4. Transfusion Rates
5. Intraoperative Complication Rates
6. 30 Day Post-operative Complication Rates
7. 30 Day Readmission Rates
8. 30 Day Reoperation Rates
9. 30 Day Mortality Rates

VIII. CONCLUSION

The *da Vinci Xi* and *X* Surgical Systems (models IS4000 and IS4200) have the same intended use as the predicate devices, as demonstrated by the RWE to support the safety and effectiveness for the new labeled use of the representative, specific duodenal switch bariatric surgical procedures of: Biliopancreatic Diversion-Duodenal-Switch/BPD-DS, Single Anastomosis-Duodeno Ileal Bypass with Sleeve/SADI-S, One Anastomosis Duodenal Switch/OADS, and Transit Bipartition under the "general laparoscopic surgical procedure" Indications for Use as compared to the predicate devices. In addition, the subject devices have the same technological characteristics as the predicate devices. Therefore, the *da Vinci Xi* and *X* Surgical Systems (Models IS4000 and IS4200) are substantially equivalent to the cleared predicate devices.

TABLE 1: Unmatched and Propensity Score Matched *da Vinci* and Laparosocopic Duodenal Switch Bariatric Surgical Procedures

Outcomes	Unmatched			PS Matched		
	L	**R**	**p-value**	**L**	**R**	**p-value**
1. Operative Time (min), median (IQR)	180 (150, 240)	284 (240, 345)	<.001	210 (165, 270)	270 (240, 330)	<.001¶
2. Length of Hospital Stay (days), median (IQR)	2 (1, 3)	2 (1, 3)	0.518	2 (1, 3)	2 (1, 3)	0.372§§
3. Conversion to Open Surgery, n (%)	5 (0.3)	0 (0.0)	0.590	1 (0.3)	0 (0.0)	1.000§§
4. Transfusion Rate, n (%)	9 (0.6)	4 (1.1)	0.308	3 (1.0)	3 (1.0)	1.000
5. Intraoperative Complication Rate, n (%)	2 (0.1)	1 (0.3)	0.490	1 (0.3)	1 (0.3)	1.000
6. 30 Day Post-Operative Complication Rate, n (%)	309 (20.6)	86 (22.8)	0.343	85 (27.1)	67 (21.3)	0.094
7. 30 Day Readmission	84 (5.6)	14 (3.7)	0.142	28 (8.9)	10 (3.2)	0.003
8. 30 Day Reoperation	30 (2.0)	7 (1.9)	0.859	14 (4.5)	5 (1.6)	0.036
9. 30 Day Mortality	2 (0.1)	0 (0.0)	1.000	1 (0.3)	0 (0.0)	1.000

§§ No adjustment to the p-value according to the step-down approach described in section 5.2.1. We started with the p-value for OR time first and then LOS, p-value of LOS greater that the significance level was observed therefore the adjustment method stopped.