May 12, 2023

Intuitive Surgical, Inc.
Michael Prutton
Regulatory Affairs Specialist
1266 Kifer Road
Suunyvale, California 94086

Re: K231224
Trade/Device Name: da Vinci Xi Surgical System (IS4000), da Vinci X Surgical System (IS4200)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 27, 2023
Received: April 28, 2023

Dear Michael Prutton:

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: 2023.05.12 09:25:59 -04'00'

Mark Trumbore, Ph.D.
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.

Submission Number *(if known)*

Device Name

da Vinci Xi Surgical System (IS4000);
da Vinci X Surgical System (IS4200)

Indications for Use *(Describe)*

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Models: IS4000 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.

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.

510(k) Summary (21 CFR § 807.92)

I. Submitter Information

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Michael Prutton
Regulatory Affairs Specialist
Michael.Prutton@intusurg.com
408-317-8653

Date Summary Prepared: May 10, 2023

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:	Special 510(k)

III. Predicate Device Information

Predicate Devices: Intuitive Surgical da Vinci Xi Surgical System, Model IS4000 (K131861)
Intuitive Surgical da Vinci X Surgical System, Model IS4200 (K171294)

IV. Device Description

This 510(k) is for a labeling modification only, to include the following additional representative, specific procedure of "Appendectomy" 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). 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.

VI. Comparison of Indications for Use

The indications for use are the same.

VII. Technological Comparison

This application is for a change to the labeling only. 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.

VIII. Non-Clinical and/or Clinical Tests Summary & Conclusions

The appendix is a small, tube-like structure that is attached to the Cecum of the large intestine. The appendix is removed during an appendectomy procedure, commonly used to treat appendicitis. It is also removed *en bloc* with the specimen during a right colectomy procedure, which is a covered procedure under the umbrella procedure Low Anterior Resection Total Mesorectal Excision (LAR/TME) which was cleared under K171632. A comparison of the surgical tasks performed with the da Vinci Surgical Systems for appendectomy shows that there are no new surgical tasks introduced by the appendectomy as compared to the colorectal umbrella procedure of LAR/TME and covered procedure Colectomy. They employ the same surgical tasks in the same anatomical location of the abdomen.

The surgical risks associated with appendectomy are not different than those associated with Low Anterior Resection Total Mesorectal Excision (LAR/TME) and Colectomy. They include: 1) bleeding; 2) infection; 3) leak; 4) stricture; 5) bowel injury; 6) injury to adjacent organs; and 7) perforation.

Appendectomy is a covered procedure under the umbrella procedure of Low Anterior Resection Total Mesorectal Excision (LAR/TME) and covered procedure Colectomy based on the following:

1. All procedural steps, surgical tasks, and instruments required to perform appendectomy with the da Vinci Xi or X Surgical Systems are part of the umbrella procedure.

2. Appendectomy is less complex and less challenging than the umbrella procedure.
3. All anatomical structures encountered in appendectomy are encountered similarly in the umbrella procedure.
4. Use of the da Vinci Xi or X Surgical Systems to perform appendectomy does not introduce any new issues of safety or effectiveness as compared to device usage in the cleared umbrella procedure.

Appendectomy can be completed using the da Vinci Xi or X Surgical Systems without introducing any different issues of safety or effectiveness as compared to the representative, specific general laparoscopic surgical procedures previously cleared for the Xi and X systems. The addition of appendectomy as a representative, specific procedure does not represent a change or modification in the device that could significantly affect the safety or effectiveness of the device, thus requiring no new clinical data or other validation/verification testing to evaluate safety or effectiveness of the device.