DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 26, 2017

Intuitve Surgical, Inc.
Mr. Brandon Hansen
Project Manager, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K171294
Trade/Device Name: da Vinci X Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 28, 2017
Received: May 2, 2017

Dear Mr. Hansen:

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 -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)*
K171294

Device Name
da Vinci X Surgical System

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)

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Brandon Hansen
Regulatory Affairs
Phone Number: 408-523-7485
Fax Number: 408-523-8907
Email: brandon.hansen@intusurg.com

Date Summary Prepared: May 1, 2017

Trade Name: *da Vinci*® *X* Surgical System

Common Name: Endoscopic instrument control system

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Codes: NAY (System, Surgical, Computer Controlled Instrument)

Classification Advisory Committee: General and Plastic Surgery

Predicate Device: *da Vinci*® *Xi*™ Surgical System device, K131861

Device Description

The *da Vinci X* Surgical System, Model IS4200 is a modification to the Patient Side Cart of the *da Vinci Xi* Surgical System, Model IS4000, cleared under K131861. The arms of the IS4000 have been grafted onto the setup structure of the *da Vinci Si* Surgical System Patient Cart (K081137). The *da Vinci X* Patient Cart utilizes the same electronics as the *da Vinci Xi* Patient Cart with some minor modifications. The *da Vinci X* Patient Cart is run by the same software and is to be used with the Surgeon Console and Vision Cart of the *da Vinci Xi* Surgical System. All of the *da Vinci Xi* instruments and accessories, including advanced instruments (e.g., Single Site, Vessel Sealer, Stapler, etc.), are compatible with the *da Vinci X* Surgical System.

The *da Vinci X* Surgical System is a software-controlled, electro-mechanical system designed for surgeons to perform minimally invasive surgery. The *da Vinci X* Surgical System consists of a Surgeon Console, a Patient Cart, and a Vision Cart and is used with an Endoscope, *EndoWrist* Instruments, and Accessories.

The surgeon seated at the Surgeon Console controls all movement of the *EndoWrist* Instruments and Endoscope by using two Master Controls and a set of foot pedals. The surgeon views the three-dimensional endoscopic image on a High Resolution Stereo Viewer (3D Viewer), which

provides him/her a view of patient anatomy and instrumentation, along with icons and other user interface features.

The Vision Cart includes the supporting electronic and video processing equipment for the system.

The Patient Side Cart is positioned at the operating room table and has four endoscope/instrument arms that are positioned over the target patient anatomy. An endoscope attaches onto one arm and provides the surgeon a high resolution, three-dimensional view of the patient anatomy. A suite of *EndoWrist* Instruments are attached/detached from the arms, enabling the surgeon to perform various surgical tasks. Accessories such as cannulas, obturators, seals, and drapes are also needed to perform procedures with the system. The *da Vinci X* Surgical System Patient Cart has the same arms as the *da Vinci Xi* Surgical System Patient Cart and is compatible with all of the base, *Single-Site,* and advanced instruments and accessories (with the exception of the column drape) cleared for use with the *da Vinci Xi* Surgical System (K131861).

Intended Use/Indications for Use:

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.

Technological Characteristics:

In terms of technological characteristics, the *da Vinci X* Surgical System is substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device, cleared under K131861. The *da Vinci X* Surgical System uses the same Surgeon Console, Vision Cart, Software, Instruments, and Accessories as the predicate *da Vinci Xi* Surgical System.

Performance Data:

Performance test data demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. Hardware verification, human factors testing, and preclinical validation testing were performed. Software

testing was also conducted to support this modification. The software testing included user interface, algorithm, and software verification/validation testing.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the *da Vinci X* Surgical System is substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device, cleared under K131861.