July 16, 2025

Intuitive Surgical, Inc.
Changxin Xu
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K251202
Trade/Device Name: da Vinci Surgical System (IS5000)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 16, 2025
Received: April 18, 2025

Dear Changxin Xu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.07.16 09:34:04 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251202

Device Name
da Vinci Surgical System, Model IS5000

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS5000) shall 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 and general thoracoscopic surgical procedures. The system is indicated for adult 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.

Contraindication:
Use of the force feedback needle driver is contraindicated in hysterectomy and myomectomy due to the risk of vaginal bleeding requiring hospital readmission and/or the need for additional procedures. The use of non-force feedback needle drivers is recommended for suturing in these procedures.

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

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact Person:	Changxin Xu Senior Regulatory Affairs Specialist Phone: +1-408-218-9360 Email: Changxin.xu@intusurg.com

Date Prepared:	April 16, 2025

II. Subject Device Information

Trade Name:	da Vinci Surgical System, Model IS5000
Common Name:	System, Surgical, Computer Controlled Instrument
Classification Name:	Endoscope and Accessories (21 CFR § 876.1500)
Regulation Medical Specialty:	Gastroenterology/Urology
Review Panel:	General and Plastic Surgery
Product Code:	NAY
Classification:	Class II

III. Predicate Device Information

Predicate Device:	da Vinci Surgical System, Model IS5000 (K232610)
Reference Device:	da Vinci Surgical System, Model IS4000 and IS4200 (K242427)

IV. Device Description

The da Vinci Surgical System, Model IS5000, is a software-controlled, electro-mechanical system designed to enable complex surgery using a minimally invasive approach. The system consists of a Console (Surgeon Console or SSC), a Robot (Patient Side Cart or PSC), and a Tower (Vision Side Cart or VSC) and is used with an endoscope, instruments, and accessories.

The basis for this submission is the modification of the da Vinci Surgical System, Model IS5000, cleared under K232610. The device software is being modified to include a new feature called "Networked Central Configuration Management" which enables Intuitive technical support to remotely push configuration data to a system connected to the network for user to update the system. The configuration data includes customer site preference settings and system feature enabling or disabling. The modification also includes changes to the device labeling.

V. Intended Use/Indications for Use

Intended use and indications for use for the subject da Vinci Surgical System, Model IS5000, are unchanged from the predicate device.

Intended Use:
To assist in the accurate control of endoscopic instruments in minimally invasive surgery.

Indications for Use:
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS5000) shall 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 and general thoracoscopic surgical procedures. The system is indicated for adult 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.

<u>Contraindication:</u>

Use of the force feedback needle driver is contraindicated in hysterectomy and myomectomy due to the risk of vaginal bleeding requiring hospital readmission and/or the need for additional procedures. The use of non-force feedback needle drivers is recommended for suturing in these procedures.

VI. Technological Characteristics

The subject da Vinci Surgical System, Model IS5000, is technologically similar to the predicate device. The principles of operation are unchanged. The technological differences that are the basis for this submission are limited to updated system software that enables the Networked Central Configuration Management feature in the subject devices.

VII. Performance Data

<u>Software Testing</u>

Software verification and validation have been conducted at the unit, integration, and system level to confirm that the subject device continues to meet design requirements and user needs. Software documentation has been provided in accordance with FDA Guidance *Content of Premarket Submissions for Device Software Functions,* issued on June 14, 2023.

<u>Cybersecurity Testing</u>

Cybersecurity verification and validation have been conducted to confirm that the risk control measures based upon the cybersecurity threat model are adequate. Cybersecurity documentation has been provided in accordance with FDA Guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, issued on September 27, 2023.

VIII. Conclusion

Based on the intended use, indications for use, technological characteristics, and performance data, the subject da Vinci Surgical System, Model IS5000, is substantially equivalent to and is as safe, as effective, and performs as well as the predicate device.