



U.S. FOOD & DRUG
ADMINISTRATION

July 23, 2025

Intuitive Surgical, Inc.
Jennifer Karafin
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K251213

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: June 24, 2025
Received: June 24, 2025

Dear Jennifer Karafin:

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: 2025.07.23 14:46:14 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251213

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Please provide the device trade name(s).

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Da Vinci Surgical System (IS5000)

Please provide your Indications for Use below.

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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.

Please select the types of uses (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

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086-5304 USA
Contact:	Jennifer Karafin Senior Regulatory Affairs Specialist Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086-5304 USA Phone: +1-315-447-6522 Email: jennifer.karafin@intusurg.com
Date Summary Prepared:	April 16, 2025
Trade Name:	Da Vinci Surgical System, Model IS5000
Common Name:	Endoscopic instrument control system
Classification:	Class II, 21 CFR 876.1500, Endoscope and Accessories
Product Code:	NAY (System, Surgical, Computer Controlled Instrument)
Review Panel:	General & Plastic Surgery
Predicate Devices:	Da Vinci Surgical System, Model IS5000 (K232610)

Device Description:

The da Vinci Surgical System, Model IS5000 (**da Vinci 5**) is a software-controlled, electro-mechanical system designed to enable complex surgery using a minimally invasive approach. The system consists of a Console, Robot, and Tower and is used with an endoscope, instruments, and accessories.

The basis for this submission is a modification to the da Vinci Surgical System, Model IS5000, cleared under **K232610**. The device software has been modified to include a new “force gauge” graphical user interface element, which provides a visual representation of forces applied while completing tasks with the da Vinci Force Feedback instruments.¹ The modification also includes changes to the device labeling.

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.

¹ The da Vinci Force Feedback Instruments are force sensing endoscopic instruments that are compatible with the da Vinci Surgical System, Model IS5000. These existing devices, most recently cleared under **K243641**, have not been modified for the subject device changes.

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.

Technological Characteristics:

The subject da Vinci Surgical System, Model IS5000 (da Vinci 5) is technologically similar to its predicate device. The overall technological characteristics such as principles of operation are unchanged. The change that is the basis for this submission includes a software modification to enable the new force gauge graphical user interface element.

Performance Data:

The following performance data demonstrates substantial equivalence to the predicate device. All testing passed and supports the subject device changes:

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

Human Factors Information: Human factors information has been provided in accordance with recommendations for HF Submission Category 3 in FDA Draft Guidance *Content of Human Factors Information in Medical Device Marketing Submissions*, issued on December 9, 2022. Based on the results of a comparative task analysis (CTA) and use-related risk analysis (URRA), human factors validation has been conducted for impacted existing critical tasks.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject da Vinci Surgical System, Model IS5000 (da Vinci 5) is substantially equivalent to and is as safe, as effective, and performs as well as its predicate device.