December 16, 2024

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

Re: K243641
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: November 25, 2024
Received: November 26, 2024

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: 2024.12.16 11:30:24 -05'00'

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.

Submission Number *(if known)*

Device Name

da Vinci Surgical System (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

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

Contact: Jennifer Karafin
Senior Regulatory Affairs Specialist
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1266 Kifer Road,
Sunnyvale, CA 94086
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Email: jennifer.karafin@intusurg.com

Date Summary Prepared: November 25, 2024

Trade Name: Da Vinci Force Feedback Instruments

Common Name: Endoscopic instruments and accessories

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 Force Feedback Instruments (K232610, K241284)

Device Description:

The da Vinci Force Feedback Instruments are 8 mm, multi-use, endoscopic instruments intended for use with the da Vinci Surgical System, Model IS5000. These instruments have been designed with an articulating wrist that gives surgeons natural dexterity and range of motion, and have the ability to render forces measured at the instrument tip to the hand controls at the system Console.

The basis for this submission is a modification to the reprocessing instructions, in addition to an increase in the number of surgical uses (lives) and reprocessing cycles for devices in the da Vinci Force Feedback Instrument family as listed in **Table 1**, which Intuitive intends to introduce into interstate commerce in accordance with 21 CFR Section 807.81.

Table 1: Subject and Predicate Device Number of Uses and Reprocessing Cycles

Device	Subject Device			Predicate Device			Predicate Submission Number
	Model #	Number of Uses	Number of Reprocessing Cycles	Model #	Number of Uses	Number of Reprocessing Cycles	
Da Vinci Force Feedback Large Needle Driver	476006	6	9	475006	3	5	K232610
Da Vinci Force Feedback Cadiere Forceps	476049	6	9	475049	3	5	K232610
Da Vinci Force Feedback Maryland Bipolar Forceps	476172	6	9	475172	3	5	K232610
Da Vinci Force Feedback Fenestrated Bipolar Forceps	476205	6	9	475205	3	5	K232610
Da Vinci Force Feedback ProGrasp Forceps	476093	6	9	475093	4	6	K241284
Da Vinci Force Feedback Mega SutureCut Needle Driver	476309	6	9	475309	4	6	K241284

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.

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 Force Feedback Instruments are technologically similar to their predicate devices. The overall technological characteristics such as principles of operation are unchanged. The changes that are the basis for this submission include modifications to the performance specifications and design to increase the number of uses and reprocessing cycles.

Performance Data:

The following performance testing was conducted to demonstrate substantial equivalence to the predicate devices. All testing passed and supports the subject device changes:

Cleaning Validation: Cleaning validation was performed to validate the efficacy of the manual cleaning process in accordance with the following standards and guidance documents:

- ANSI/AAMI ST98:2022 - Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- AAMI TIR12:2020 - Technical Information Report - Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
- ASTM F3208-20 - Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
- FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued on March 17, 2015 (amended on June 9, 2017)

Reliability (Life) Verification: Instruments were subjected to sufficient reprocessing and simulated surgical use cycles to simulate their design life. Testing included benchtop performance measurements, visual inspection, and evaluation of functional performance to verify instrument mechanical and sensor performance at each cycle.

Dielectric Strength Testing: Dielectric strength testing was performed in accordance with IEC 60601-2-2:2017 (Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories). This testing was also conducted to fulfill FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical*

Devices for General Surgery, issued on March 9, 2020. Testing was conducted after subjecting the instruments to sufficient reprocessing and simulated surgical use cycles to simulate their design life.

Jaw Force to Failure Verification: Jaw force to failure verification was performed after subjecting the instruments to sufficient reprocessing and simulated surgical use cycles to simulate their design life. This testing was conducted to fulfill FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*, issued on March 9, 2020.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject da Vinci Force Feedback Instruments are substantially equivalent to and are as safe, as effective, and perform as well as their predicate devices.