



July 3, 2024

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

Re: K241284

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: May 3, 2024
Received: May 7, 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.

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: 2024.07.03
08:05:10 -04'00'

Mark Trumbore
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

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.

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510(k) Summary

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

Contact: Jennifer Karafin
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Date Summary Prepared: May 3, 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 and Plastic Surgery

Predicate Devices: da Vinci Force Feedback Instruments (K232610)

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 changes that are the basis for this submission are increasing the number of surgical uses (lives) and reprocessing cycles for the subject da Vinci Force Feedback Mega SutureCut Needle Driver and da Vinci Force Feedback ProGrasp Forceps compared to their respective predicate devices cleared in K232610, as summarized in **Table 1** below.

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

Device	Model Number	Predicate Devices (K232610)		Subject Devices	
		Number of Uses	Number of Reprocessing Cycles	Number of Uses	Number of Reprocessing Cycles
da Vinci Force Feedback Mega SutureCut Needle Driver	475309	1	3	4	6
da Vinci Force Feedback ProGrasp Forceps	475093	1	3	4	6

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 Mega SutureCut Needle Driver and da Vinci Force Feedback ProGrasp Forceps are technologically similar to their respective predicate devices. Changes that are the basis for this submission are limited to programming an increased number of uses into the instrument, and listing a higher number of uses and reprocessing cycles in the reprocessing manual.

Performance Data:

The following performance testing was conducted to demonstrate substantial equivalence to the predicate devices. All testing passed and supports the subject devices' increased number of uses and reprocessing cycles.

Reliability (Life) Testing: 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.

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 respective predicate devices.