



March 11, 2026

Intuitive Surgical, Inc.
Claire Bao
Senior Regulatory Affairs Specialist
1266 Kifer Rd.
Sunnyvale, California 94086

Re: K253986
Trade/Device Name: da Vinci Force Feedback Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: February 27, 2026
Received: February 27, 2026

Dear Claire Bao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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: 2026.03.11 08:55:43 -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.

K253986

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Please provide the device trade name(s).

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da Vinci Force Feedback Instruments

Please provide your Indications for Use below.

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The da Vinci Force Feedback Instruments are 8 mm, multi-use endoscopic instruments intended to be used with the da Vinci Surgical System, Model IS5000. These instruments have an articulating wrist that gives surgeons natural dexterity and range of motion, and possess the ability to render forces measured at the instrument tip to the hand controls at the Surgeon Console of the IS5000 System. Each instrument performs one or more surgical tasks such as suturing, grasping, and tissue manipulation.

Indications for use of the da Vinci Force Feedback Instruments are covered as part of the da Vinci Surgical System, Model IS5000. The most recent cleared indications for use, which are not anticipated to be modified in the upcoming 510(k), are listed for reference below.

Da Vinci Surgical System, Model IS5000:

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 ([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

Official Contact: Claire Bao
Senior Regulatory Affairs Specialist
Phone: +1-213-610-3589
Email: Claire.Bao@intusurg.com

Date Prepared: December 11, 2025

I. Subject Device:

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

II. Predicate Device:

Predicate Devices: da Vinci Force Feedback Instruments (K243641)

III. 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 devices listed in [Table 1](#) below are the subject devices of this premarket notification, which Intuitive intends to introduce into interstate commerce in accordance with 21 CFR Section 807.81.

Table 1: Subject Devices

Model Number	Device Description
477006	da Vinci Force Feedback Large Needle Driver
477049	da Vinci Force Feedback Cadiere Forceps
477093	da Vinci Force Feedback ProGrasp Forceps
477172	da Vinci Force Feedback Maryland Bipolar Forceps
477205	da Vinci Force Feedback Fenestrated Bipolar Forceps
477309	da Vinci Force Feedback Mega SutureCut Needle Driver

IV. 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.

V. Technological Characteristics:

The subject da Vinci Force Feedback Instruments have the same intended use and fundamental scientific technology as 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 product design and cleaning method driven by updates to the cleaning architecture, as well as an increase in the maximum number of surgical uses (lives) and reprocessing cycles. Additional changes include the incorporation of compatible sterilization container, labeling and software updates. These changes do not substantively change the safety and performance of the subject device relative to the function of the predicate device.

VI. Performance Data:

The following performance testing was conducted to demonstrate substantial equivalence to the predicate devices. Testing included cleaning validation, sterilization validation, packaging, biocompatibility, electrical safety and EMC, software, and a set of bench performance testing. All testing passed and supported the subject device changes:

Cleaning Validation

Cleaning validation testing was performed 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)

Sterilization Validation

Sterilization validation testing was performed in accordance with the following standards and guidance documents:

- AAMI TIR 12:2020/(R)2023 – Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ISO 17664-1:2021 - Processing of health care products – Information to be provided by the manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices
- ANSI/AAMI/ISO 17665-1:2006/(R)2013 - Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 14937:2009/(R)2013 – Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for 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)

Packaging Validation

Packaging validation testing was performed in accordance with ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems.

Biocompatibility

Biological Safety Evaluation and Biocompatibility testing was completed in accordance with the following standards and guidance documents:

- FDA Guidance: Use of International Standard ISO 10993, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process”, issued on September 8, 2023
- ISO 10993-1: 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Electrical Safety and EMC Testing

Electrical Safety, Electromagnetic Compatibility and Dielectric Strength testing were completed in accordance with the following standards and guidance documents:

- ANSI/AAMI ES 60601-1: 2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance [FDA Recognition No. 19-46]
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATION VERSION: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard, Electromagnetic Compatibility – Requirements and Tests [FDA Recognition No. 19-36]
- IEC 60601-2-2: 2017 (Sixth Ed.) Particular Requirements for Basic Safety and Essential Performance of High Frequency Surgery Equipment and High Frequency Surgical Accessories [FDA Recognition No. 6-389]

- FDA Guidance *Electromagnetic Compatibility (EMC) of Medical Devices*, issued on June 6, 2022
- FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*, issued on March 9, 2020

Software Testing

Software testing was performed in accordance with the following standards and guidance documents:

- ANSI/AAMI/IEC 62304 – Medical Device Software – Software Life Cycle Processes
- FDA Guidance *Content of Premarket Submissions for Device Software Functions*, issued on June 14, 2023

Cybersecurity Testing

Cybersecurity verification and penetration testing were completed in accordance with following guidance document:

- FDA Guidance *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*, issued on June 27, 2025

Performance Testing – Bench

- Reliability (Life) Verification
- Jaw Force to Failure Verification
- Sensor Verification
- Mechanical Verification
- Stress Corrosion Verification
- System Compatibility Verification

VII. Conclusion:

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.