



March 14, 2024

Intuitive Surgical, Inc.  
Melissa Gonzalez  
Project Manager, Regulatory Affairs  
1266 Kifer Road  
Sunnyvale, California 94086

Re: K232610

Trade/Device Name: da Vinci Surgical System Model IS5000, da Vinci Insufflator and Tube Set with  
Smoke Evacuation

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope And Accessories

Regulatory Class: Class II

Product Code: NAY

Dated: February 9, 2024

Received: February 12, 2024

Dear Melissa Gonzalez:

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](mailto: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: 2024.03.14  
09:52:43 -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

510(k) Number (if known)  
K232610

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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## Indications for Use

510(k) Number (if known)  
K232610

Device Name  
da Vinci Insufflator and Tube Set with Smoke Evacuation

### Indications for Use (Describe)

The da Vinci Insufflator with compatible tube sets is intended for use in diagnostic and/or therapeutic endoscopic and thoracoscopic procedures to distend a cavity by filling it with gas. Intended cavities for this device include abdominal and thoracic cavities in adult and bariatric patients.

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)

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## Indications for Use

510(k) Number (if known)  
K232610

Device Name  
Stainless Steel Endoscope Reprocessing Tray, 8mm, Gen5

### Indications for Use (Describe)

The Intuitive da Vinci® 5 endoscope tray is intended for use to encase and protect compatible da Vinci endoscopes for sterilization in any of the following sterilization machines and cycles:

- STERRAD 100NX sterilization system using the Flex, Express, and DUO cycles
- STERIS V-PRO maX 2 using the Non Lumen, Flexible, or Lumen cycles
- STERIS V-PRO maX using the Non Lumen, Flexible, or Lumen cycles
- STERIS V-PRO 1 Plus using the Non Lumen or Lumen cycles
- STERIS V-PRO 1 using the V-PRO/Lumen cycle

The sterilization-cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one da Vinci 5 endoscope. The length of the da Vinci 5 endoscopes is approximately 600 mm and the diameter of the shaft is 8.8 mm. The maximum weight of the tray and endoscope is 13 lbs. The endoscope tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally-marketed, validated, FDA-cleared STERRAD and STERIS V-PRO compatible sterilization wrap in order to maintain sterility of the enclosed medical instrument.

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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## 5 510(k) Summary

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

**Contact:** Melissa S. Gonzalez  
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Intuitive Surgical, Inc.  
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**Date Summary Prepared:** March 12, 2024

**Trade Name:** da Vinci Surgical System Model IS5000/Gen5  
da Vinci Insufflator and Tube Set with Smoke Evacuation  
da Vinci Endoscope Tray

**Common Name:** Endoscopic instrument control system, endoscopic instruments and accessories  
Insufflator, laparoscopic

**Classification:** Class II, 21 CFR 876.1500, Endoscope and Accessories  
Class II, 21 CFR 884.1730, Insufflator, Laparoscopic

**Product Code:** NAY (System, Surgical, Computer Controlled Instrument)  
HIF (Insufflator, Laparoscopic)  
GCJ (Laparoscope, General & Plastic Surgery)  
KCT (Sterilization Wrap Containers, Trays, Cassettes & Other Accessories)

### Classification Advisory

**Committee:** General and Plastic Surgery  
Obstetrics and Gynecology  
General Hospital

**Predicate Devices:** Intuitive Surgical da Vinci Surgical System, Model IS4000 (K131861, with subsequent clearances for additional features, instruments, accessories – K141077, K151794, K152892, K161271, K191529; and representative uses - K152578, K153276, K161178, K170713, K171632, K171699, K172086, K172643, K173585, K173842, K182140, K183086, K202834, K211784, K223080, K231224) World of Medicine Pneumoclear Insufflation System (K201361) Endoscope Sterilization Tray (K183139)

**Reference Device:** K171120 Senhance Surgical Robotic System (force feedback instruments)  
K190303 AirSeal iFS System

**Device Description:**

da Vinci Surgical System, Model IS5000:

The da Vinci Surgical System Model IS5000/Gen5 is a software-controlled, electromechanical system designed for surgeons to perform minimally invasive surgery. It consists of a Surgeon Side Console (Console), a Patient Side Cart (Robot), and a Vision System Cart (Tower) and is used with an Endoscope, EndoWrist Instruments, and Accessories.

The da Vinci Surgical System Model IS5000/Gen5 is a modification to the da Vinci Xi Surgical System Model IS4000 with the same core features. The IS5000 System further integrates supporting surgical devices, such as an updated electrosurgical generator (E-200) and an integrated insufflator. The instruments and accessories compatible with the IS4000 System are also compatible with the IS5000 System, with an additional set of force feedback instruments designed specifically for the IS5000 System. These Force Feedback instruments (including Large Needle Driver, MegaSutureCut Needle Driver, Cadiere Graspers, Fenestrated Bipolar Forceps, and Maryland Bipolar Forceps) are similar to the Xi instruments with the addition of a sensor that translates directional forces at the instrument back to the surgeon through the hand controls on the Console.

**da Vinci Insufflator**

The da Vinci Insufflator is a pneumatic device, integrated into the system Tower, which connects to house or tank CO2 gas through the Tower insufflation manifold. It is operated through controls and indicators on each of the Tower, Console, or Robot touchscreens.

**Endoscope Tray**

The endoscope tray is a stainless steel sterilization tray to encase and protect da Vinci endoscopes during reprocessing.

**Intended Use:**

**da Vinci Surgical System, Model IS5000**

To assist in the accurate control of endoscopic instruments during minimally invasive surgery.

**da Vinci Insufflator and Tube Set with Smoke Evacuation**

To distend the abdominal and/or thoracic cavity during diagnostic and/or therapeutic endoscopic and thoracoscopic procedures.

**da Vinci Endoscope Tray**

To encase and protect da Vinci endoscopes for sterilization

**Indications for Use:****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.

**da Vinci Insufflator and Tube Set with Smoke Evacuation**

The da Vinci Insufflator with compatible tube sets is intended for use in diagnostic and/or therapeutic endoscopic and thoracoscopic procedures to distend a cavity by filling it with gas. Intended cavities for this device include abdominal and thoracic cavities in adult and bariatric patients.

**da Vinci Endoscope Tray**

The Intuitive da Vinci 5 endoscope tray is intended for use to encase and protect compatible da Vinci endoscopes for sterilization in any of the following sterilization machines and cycles:

- STERRAD 100NX sterilization system using the Flex, Express, and DUO cycles
- STERIS V-PRO maX 2 using the Non Lumen, Flexible, or Lumen cycles
- STERIS V-PRO maX using the Non Lumen, Flexible, or Lumen cycles
- STERIS V-PRO 1 Plus using the Non Lumen or Lumen cycles
- STERIS V-PRO 1 using the V-PRO/Lumen cycle

The sterilization-cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one da Vinci 5 endoscope. The length of the da Vinci 5 endoscopes is approximately 600 mm and the diameter of the shaft is 8.8 mm. The maximum weight of the tray and endoscope is 13 lbs. The endoscope tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally-marketed, validated, FDA-cleared STERRAD and STERIS V-PRO compatible sterilization wrap in order to maintain sterility of the enclosed medical instrument.

**Technological Characteristics:**

The da Vinci Surgical System, Model IS5000 based on the da Vinci Xi Surgical system and therefore is technologically similar to the da Vinci Xi Surgical System, Model IS4000. Both systems have a Console, Tower and Robot. The Robot architecture is identical and therefore, the Model IS5000 is compatible with a subset of the Model IS4000 instruments and accessories. The new Force Feedback instruments are modifications of the IS4000 instruments to include force feedback sensor technology. The IS5000 includes a new integrated insufflator and like the IS4000 also has an Electrical Surgical Unit on the Tower.

The System software has been updated to include new UI features (i.e. head-in menu, digital swap, instrument tracking, and new system menu) as well as support for hardware design changes.

All system Carts contain updated electronics to include the latest technology. In addition, the Console and Tower have updated form factor.

The Surgeon Console is identical to the predicate in core functions and similar in design. The 3D viewer is smaller and more maneuverable and the MTMs have been modified to enable the ability to transmit haptic feedback from the Force Feedback instruments to the user.

The Tower has an updated 4K overhead monitor, new front touchscreen, integrated Electro Surgical Unit (cleared separately under K223039), integrated Insufflator and associated High Flow Insufflator Tube Set, and modified endoscope connector on the Endoscope System Controller (ESC).

The Model IS5000 Endoscopes have a modified connector to accommodate the modified ESC hardware and a tip heater.

A set of six (6) Force Feedback enabled instruments have been added to the existing IS4000 instruments which are now compatible with the da Vinci Surgical System, Model IS5000. The Force Feedback instruments are only compatible with the IS5000 System, they are not backward compatible with the IS4000 System.

Two 8mm Cannulas (standard and long) are also being introduced to support the High Flow Insufflator Tube Set. The only modification to the cannulas is hexagonal tip geometry which alters the airflow through the cannulas.

**Performance Data:**

The following performance testing was conducted to demonstrate substantial equivalence to the predicate devices.

**Bench testing** demonstrates that the subject devices design output meets the design input requirements and that the devices perform as intended. The testing conducted consisted of dimensional measurements, mechanical and functional verification, and simulated use in animal and cadaver models.

**Electrical Safety and Electromagnetic Compatibility** testing was conducted using a third-party lab in accordance with the current versions of IEC 60601-1 (basic safety and essential performance), IEC 60601-1-2 (Electromagnetic disturbances), IEC 60601-2-18 (Endoscopic equipment interactions), IEC 60601-2-2 (high frequency surgical equipment) and IEC 60825-1 (laser safety).

**Software verification and validation** testing was performed following the same software development processes and test methodology used for the predicate device. In consideration of the device risk, the software documentation level is classified as a “Enhanced” and documentation was provided as recommended in FDA’s Guidance for Industry and FDA Staff “Content of Premarket Submissions for Device Software Functions”.

**Cybersecurity** information demonstrating compliance with section 524B of the FD&C Act consistent with current “FDA Guidance: Cybersecurity in Medical Devices - Quality System Considerations and Content of Premarket Submissions” was provided in this submission.

**Human Factors data** assessed the use-safety and effectiveness of the da Vinci Surgical System, Model IS5000 for the intended uses, user groups and use environments. Surgeon and OR Staff participants were observed to determine their ability to safely complete simulated surgical tasks and high-risk use scenarios related to Critical Tasks. Results of this study, including observed performance and subjective feedback, demonstrate that the da Vinci Surgical System, Model IS5000 is safe and effective for its intended uses, users and use environment.

**Pre-clinical surgical equivalence studies (Acute and Chronic Animal data)** were performed directly comparing the safety and performance of the Intuitive Surgical da Vinci Surgical System, Model IS5000 and the Intuitive Surgical da Vinci Xi Surgical System, Model IS4000. Surgeon participants performed urologic, thoracic and colorectal surgical procedures using either canine or porcine models. Surgical safety and performance were assessed via metrics collected during testing and by veterinary pathologists’ review of histology from excised tissue.

**Clinical Data** was collected via a prospective, multi-center, single-arm confirmatory clinical investigation. The study enrolled 53 subjects across four (4) specialties treated by surgeons with a range of experience. A summary of the baseline demographics for subjects in each of the specialties is provided in **Table 1**.

*Table 1: IS5000 IDE Subject Demographics by Specialty*

Variable Name	General Surgery (N=20)	Thoracic (N=6)	Urology (N=6)	Gynecology (N=21)
<b>Age (years)</b>				
<b>Mean (SD)</b>	49.2 (12.77)	53.5 (17.72)	66.0 (3.79)	52.6 (16.02)
<b>Median</b>	49.0	54.5	67.0	51.0
<b>95% CI</b>	(43.17, 55.13)	(34.91, 72.09)	(62.02, 69.98)	(45.33, 59.91)
<b>Sex n (%)</b>				
<b>Male</b>	14 (70.0%)	1 (16.7%)	6 (100.0%)	0 (0%)
<b>Female</b>	6 (30.0%)	5 (83.3%)	0 (0%)	21 (100.0%)
<b>Race n (%)</b>				
<b>White</b>	15 (75.0%)	5 (83.3%)	4 (66.7%)	16 (76.2%)
<b>Black/African American</b>	3 (15.0%)	0 (0%)	1 (16.7%)	3 (14.3%)
<b>Other*</b>	2 (10.0%)	1 (16.7%)	1 (16.7%)	2 (9.5%)
<b>Ethnicity n (%)</b>				
<b>Hispanic or Latino</b>	2 (10.0%)	1 (16.7%)	2 (33.3%)	3 (14.3%)
<b>Not Hispanic or Latino</b>	18 (90.0%)	5 (83.3%)	4 (66.7%)	18 (85.7%)

\* Other for General Surgery includes: (1) Not Specified, (1) Hispanic. Other for Thoracic includes: (1) Not specified. Other for Urology includes: (1) Not Specified. Other for Gynecology includes: (1) Not Specified, (1) Unknown.

Subjects were followed for 30 days. This data was qualitatively compared to a retrospective review of robotic cases done by participating surgeons. There was an increase in unplanned hospital readmission due to vaginal bleeding for the subject device compared to the predicate device. There were no other remarkable differences between the data from the two (2) groups.

In the absence of conclusive safety and effectiveness data, the following contraindication has been added to the labeling.

**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.

The summary of the clinical investigation data is provided in **Table 2**.

*Table 2: Clinical Results*

	Number of Subjects	Number of Adverse Events	Number of Subjects with an Adverse Event	Number of Conversions	Number of Deaths	Number of Re-admissions	Number of re-operations
<b>General Surgery</b>	20	3	3	0	0	0	0
<b>Thoracic</b>	6	0	0	0	0	0	0
<b>Urology</b>	6	1	1	0	0	0	0
<b>Gynecology</b>	21	5	4	0	0	2	1
<b>Total</b>	53	9	8	0	0	2	1

In addition to the clinical assessments, human factors assessments were performed. The results of those assessments were that there were no use errors that resulted in serious patient or user harm. The study confirmed safety, effectiveness, and usability of the Intuitive Surgical da Vinci Surgical System, Model IS5000 in performing robotic-assisted surgical procedures.

**Summary:**

Based on the intended use, indications for use, technological characteristics and performance data, the Intuitive Surgical da Vinci Surgical System, Model IS5000, and da Vinci Insufflator and Tube Set with Smoke Evacuation are substantially equivalent to their respective predicate devices, the Intuitive Surgical da Vinci Xi Surgical System, Model IS4000, the World of Medicine Pneumoclear Insufflation System and the endoscope sterilization tray.