February 28, 2025

Intuitive Surgical, Inc.
Manjunath Ramappa Bisalehalli
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K243582
Trade/Device Name: da Vinci SP Advanced Access Port Kit (432701)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: January 29, 2025
Received: January 29, 2025

Dear Manjunath Ramappa Bisalehalli:

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: 2025.02.28 14:52:36 -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)*

K243582

Device Name

da Vinci SP Advanced Access Port Kit (432701)

Indications for Use *(Describe)*

The SP Advanced Access Port Kit is intended to be used in endoscopic surgery to provide access for da Vinci SP instruments, a da Vinci SP Endoscope, and assist instruments through a single port.

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	Manjunath Bisalehalli Sr. Regulatory Affairs Specialist Cell Phone Number: 412-298-4604 Email: Manjun.RamappaBisalehalli@intusurg.com
Date Summary Prepared	November 19, 2024
Trade Name	*da Vinci SP* Surgical System, Model SP1098, EndoWrist *SP* Instruments, and Accessories
Common Name	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500, Endoscope and Accessories
Product Codes	NAY (System, Surgical, Computer Controlled Instrument)
Review Panel	General and Plastic Surgery
Predicate Device(s)	*da Vinci SP* Access Port (K202571)

Device Description

The subject *da Vinci SP* Advanced Access Port Kit, Large Incision is a sterile, single-use, disposable accessory to the *da Vinci SP* Surgical System, Model SP1098, the predicate device is the cleared *da Vinci SP* Access Port Kit 510(k) #K202571). It provides surgical access for the SP1098 system during minimally invasive robotic surgery. The *da Vinci SP* Advanced Access Port Kit is compatible with the existing EndoWrist *SP* Instruments, *SP* Endoscope, and manual laparoscopic instruments (referred to as "assist instruments") and other compatible laparoscopic devices through a single incision while maintaining insufflation, which is identical to the predicate device. It is also compatible with Intuitive *da Vinci SP* 12mm Instruments, unlike the predicate device. The subject device enables superficial instrument articulation, like the predicate device. **Figure 1** provides an image of the *da Vinci SP* Advanced Access Port and its components.

Figure 1: *da Vinci SP* Advanced Access Port Kit

Indications for Use:

da Vinci SP Advanced Access Port Kit

The *SP* Advanced Access Port Kit is intended to be used in endoscopic surgery to provide access for *da Vinci SP* instruments, a *da Vinci SP* Endoscope, and assist instruments through a single port.

Comparison of Technological Characteristics with the Predicate Device(s)

The subject device comprises of an Advanced Access Port, a removable 12-6mm Reducer, and a Large Wound Retractor. In addition to all the existing compatibilities with the predicate device, the subject device adds new compatibility with Intuitive *da Vinci SP* 12 mm instruments.

The key differences between the subject device and predicate device, *da Vinci SP* Access Port Kit (510(k) # K202571) are:

- New Entry Guide lumen configuration (with an increased diameter from 25mm (predicate) to 32mm) to support Intuitive's 12mm instrument
- Non-removable Integrated Entry Guide with new seals
- Introduction of a Reducer (12-6mm) to support use of a third 6mm instrument through the 12mm lumen
- New magnet configuration for system identification
- Two additional chamber seals
- Reduced number of insufflation tubes and shortened tube length

Both the subject and predicate devices are single use, Ethylene Oxide (EO) sterilized devices.

Table 1: Subject Devices and Predicate Device, da Vinci SP Accessories

Subject Device SP Accessory		**Previously cleared SP Accessory (Predicate device submission, K202571)**	
***da Vinci SP* Accessory**	***da Vinci SP* Accessory Model Number**	***da Vinci SP* Accessory**	***da Vinci SP* Accessory Model Number**
da Vinci SP Advanced Access Port Kit, Large Incision	432701	*da Vinci SP* Access Port Kit, Large Incision	430075

For reference, **Table 2** includes a comparison of the indications for use of the SP1098 System with the Subject Device (*da Vinci SP* Advanced Access Port Kit) and the previously cleared SP1098 System (K242318). The are no changes being made to the *da Vinci* SP® Surgical System, Model SP1098 as part of this 510(k) submission.

Table 2. SP1098 System's Indications for Use Comparison

Characteristic	**SP1098 System** *(with subject device, da Vinci SP Advanced Access Port Kit)*	**SP1098 System** (K242318)
Indications for Use	*da Vinci SP*® Surgical System, Model SP1098 The Intuitive Surgical Endoscopic Instrument Control System (da Vinci SP Surgical System, Model SP1098) is intended to assist in the accurate control of Intuitive Surgical EndoWrist SP Instruments during urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use. EndoWrist SP Instruments Intuitive Surgical EndoWrist SP Instruments are controlled by the da Vinci SP Surgical System, Model SP1098, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, 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, and suturing through a single port. The system is indicated for urologic, colorectal, and general thoracoscopic surgical procedures that are appropriate for a single port approach; and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional.	**IDENTICAL** to the subject device

Table 3 includes a comparison of the Subject Device (*da Vinci SP* Advanced Access Port Kit) and the Predicate device (Predicate Device*, da Vinci SP* Access Port Kit cleared via K202571).

Table 3 Comparison – Subject Device and Predicate Device

Characteristic	**Subject Device** *da Vinci SP* Advanced Access Port Kit	**Predicate Device** *da Vinci SP* Access Port Kit (K202571)
	General Information	
Manufacturer	Intuitive Surgical, Inc.	**IDENTICAL** to the subject device
Trade Name	*da Vinci SP* Advanced Access Port	*da Vinci SP* Access Port
Model #	*da Vinci SP* Advanced Access Port Kit, Large Incision (432701)	*da Vinci SP* Access Port Kit, Large Incision (430075)
Common Name	Endoscope and accessories	**IDENTICAL** to the subject device
Regulation Number	21 CFR 876.1500	**IDENTICAL** to the subject device
Product Code	NAY, GCJ	**IDENTICAL** to the subject device
Device Classification	Class II	**IDENTICAL** to the subject device
Classification Advisory Committee	General and Plastic Surgery	**IDENTICAL** to the subject device
System Compatibility	Compatible with the ***SP1098 system***	**IDENTICAL** to the subject device
Principles of Operation	Facilitates accurate movement of surgical instruments and an endoscope through a single surgical port by using a	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *da Vinci SP* Advanced Access Port Kit	**Predicate Device** *da Vinci SP* Access Port Kit (K202571)
	master/slave servomechanism that incorporates servo drive and system-level motor control.	
Indications for Use	*da Vinci SP® Advanced Access Port Kit* The SP Advanced Access Port Kit is intended to be used in endoscopic surgery to provide access for da Vinci SP instruments, a da Vinci SP Endoscope, and assist instruments through a single port.	*da Vinci SP® Access Port Kit* The SP Access Port Kit is intended to be used in endoscopic surgery to provide access for da Vinci SP instruments, a da Vinci SP Endoscope, and assist instruments through a single port.
Intended Use	To assist in the accurate control of endoscopic instruments in minimally invasive surgery.	**IDENTICAL** to the subject device
Prescription use	Prescription/Physician use only	**IDENTICAL** to the subject device
Where used (hospital, home, ambulance, etc.)	Hospital	**IDENTICAL** to the subject device
Design		
Components	• Advanced Access Port, Large Incision (with integrated Entry Guide) • Wound Retractor • 12-6mm Reducer	• Access Port (small and large) • SP Short Entry Guide • Wound Retractor (small and large) • No Reducer Component
Access Port	Flexible Transparent Spherical	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *da Vinci SP* Advanced Access Port Kit	**Predicate Device** *da Vinci SP* Access Port Kit (K202571)
SP Entry Guide	• Two 6 mm lumens • One 12 mm lumen • One endoscope lumen	• Three 6 mm instrument lumens • One endoscope lumen
Incision Retraction	Wound Retractor	**IDENTICAL** to the subject device
Ability to Use Instruments Immediately Inside Incision	Yes	**IDENTICAL** to the subject device
Size Accepted for Laparoscopic Assist Instruments	• Chamber Seal: 5 mm to 10 mm • Rotating Access Port Seal: 5 mm to 12 mm	**IDENTICAL** to the subject device
Number of Chamber Seals	Three (3)	One (1)
Rotational Range of Laparoscopic Assist Instrument Insertion Around SP Instrument Cluster	270°	**IDENTICAL** to the subject device
Incision Size Range	• 2.9 cm - 7 cm (SP Advanced Access Port Kit, Large Incision, when not using SP 12mm Instrument. • 3.5 cm - 7 cm (SP Advanced Access Port Kit, Large Incision, when using SP 12mm Instrument	• Small Access Port Kit: 2.7 cm to 4 cm • Large Access Port Kit: 2.7 cm to 7 cm
Sterilization Method	Ethylene Oxide	**IDENTICAL** to the subject device
Disposable or Reusable	Disposable	**IDENTICAL** to the subject device
Biocompatibility	All patient-contacting materials are biocompatible per ISO 10993-1. For a comparison of the patient contacting	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *da Vinci SP* Advanced Access Port Kit	**Predicate Device** *da Vinci SP* Access Port Kit (K202571)
	materials for the subject vs. the predicate, and a summary of the biocompatibility testing, refer to Section 6.	
Cleaning and Disinfection Method	Single Use Device – Not Applicable	**IDENTICAL** to the subject device
Packaging	Thermoformed PETG tray, PETG retainer lid, and Tyvek lid. The packaging configuration consists of six (6) *da Vinci SP* Advanced Access Port Kits, packaged in individual cartons, and sealed in a corrugate shipper box.	Thermoformed PETG tray, PETG retainer lid, and Tyvek lid. The packaging configuration consists of six (6) *da Vinci SP* Access Port Kits, packaged in individual cartons, and sealed in a corrugate shipper box. A layer of polyurethane foam that is placed at two (2) opposite ends of the shipper box.

Performance Data:

Performance test data (bench, animal, and cadaver tests) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements.

Bench Verifications

Testing was performed on the subject device, *da Vinci SP* Advanced Access Port Kit to verify that the design meets physical, mechanical, user interface, and equipment interface requirements. A summary of the bench verification testing for the subject device is described in **Table 4**.

Table 4: Summary of the bench verification testing for the da Vinci SP Advanced Access Port Kit

Subject Device	Testing
***da Vinci SP* Advanced Access Port Kit**	1. Physical specifications 2. Mechanical requirements 3. User Interface and Patient Safety 4. Reliability 5. Environmental requirements 6. Shelf-life and Sterilization 7. Shipping and Storage 8. Package and Labeling

Cadaver and Animal Validations

Cadaver models were used to demonstrate clinical performance for anatomical access and reach for SP Instruments using *da Vinci SP* Advanced Access Port Kit. Live animal models were used to assess safety and performance for *da Vinci SP* Advanced Access Port Kit in cases where a live tissue model was required. These models replicate factors experienced during clinical use, including working with perfused organs, bleeding, normal tissue handling, and ensuring that appropriate hemostasis is achieved and maintained. Procedures were chosen on the basis of the types of surgical tasks that are performed, and which *da Vinci SP* Advanced Access Port Kit is needed for the tasks.

Human Factors

Human Factors process conducted for the subject devices included the following activities:

- Known use-related issues for predicate devices and devices similar to the subject devices were analyzed using post-market data and the MAUDE database. All identified use-related issues that are relevant to the use of the subject devices were documented in the risk analysis.

- A Comparative Task Analysis (CTA) was conducted to describe all aspects of the user-device interaction, through the breakdown of steps into user tasks, and to provide an analysis of comparison to the predicate for each task.
- A Use-Related Risk Analysis (URRA) was conducted to identify all use-related risks for each user task identified as New or Modified from the predicate in the CTA.
- Formative usability evaluations were conducted during the development process to inform the device user interface design and confirm assessment of use-related risks.

Summary:

Based on the intended use, indications for use, technological characteristics and performance data, the subject device, *da Vinci SP* Advanced Access Port is substantially equivalent to its predicate device, *da Vinci SP* Access Port Kit (K202571).