November 12, 2020

Intuitive Surgical, Inc.
Elaine Lee
Sr. Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K202571
Trade/Device Name: da Vinci SP Surgical System, Model SP1098, EndoWrist SP Instruments, and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: September 2, 2020
Received: September 4, 2020

Dear Elaine Lee:

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 (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 and the limitations described below. 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 located 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.

The OHT4: Office of Surgical and Infection Control Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

The safety and effectiveness of this device for use in the performance of general laparoscopic surgery procedures have not been established. This device is only intended to be used for single port urological procedures and for transoral otolaryngology surgical procedures in the oropharynx for benign tumors and malignant tumors classified as T1 and T2 with the da Vinci EndoWrist SP Instruments and the da Vinci SP Surgical System (SP1098).

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202571

Device Name

da Vinci SP Surgical System, Model SP1098, *EndoWrist SP* Instruments, and Accessories

Indications for Use *(Describe)*

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 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 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.

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:	Elaine Lee Senior Regulatory Engineer Phone Number: 408-523-8887 Email: Elaine.Lee@intusurg.com
Date Summary Prepared:	November 4, 2020
Trade Name:	*da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories
Common Name:	Endoscopic instrument control system, endoscopic instruments and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Code:	NAY (System, Surgical, Computer Controlled Instrument)
Predicate Device:	*da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories (K182371)
Reference Device:	GelPOINT single incision access system (Applied Medical, K090275)

Device Description

The *da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories is a software-controlled, electro-mechanical system designed for surgeons to perform minimally invasive surgery in an operating room environment. The Model SP1098 Surgical System consists of a Surgeon Console, a Patient Cart, and a Vision Cart, and is used with a Camera Instrument, *EndoWrist SP*™ Instruments, and Accessories.

The SP Access Port Kit is an ethylene oxide (EO)-sterilized, single-use, disposable accessory of the *da Vinci SP*® Surgical System. It is intended to be used in endoscopic surgery to provide access for *da Vinci SP*® instruments, a *da Vinci SP*® Camera, and

assist instruments through a single port. It can be used when superficial instrument articulation is needed.

The SP Access Port Kit is available in two sizes, differing in the range of incision sizes each kit may be used with:

- SP Access Port Kit, Small Incision (2.7 cm-4 cm)
- SP Access Port Kit, Large Incision (2.7 cm-7 cm)

Each SP Access Port Kit has three main components: the SP Short Entry Guide, the Access Port, and the Wound Retractor.

The SP Short Entry Guide has four lumens to guide the instrument and camera shafts through the Access Port. The SP Short Entry Guide is inserted through a seal at the top of the Access Port. It can rotate within the Access Port.

The Access Port is the main body of the SP Access Port Kit. The Access Port connects to the instrument arm of the SP1098 Patient Cart. The base of the Access Port connects to the Wound Retractor. Key features of the Access Port include:

- Rotating Access Port Seal: Provides access for laparoscopic assist instruments and allows rotation of the assist instrument around the SP Short Entry Guide.
- Chamber: Flexible transparent chamber provides space for articulation of the *EndoWrist SP*™ instrument joints outside the incision while maintaining insufflation and enabling visualization of surgical site.
- Chamber Seal: Provides access for insufflation accessories and laparoscopic assist instruments.
- Insufflation Lines: Provide connection to insufflator lines.

The Wound Retractor is a flexible sleeve that provides incision retraction to create access for instruments and accessories.

The two SP Access Port Kits differ only in the size of the Wound Retractor and the size of the clamp at the base of the Access Port that connects to the Wound Retractor.

Indications for Use

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 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.

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 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.

Comparison of Technological Characteristics

The subject device, *da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories, including the SP Access Port Kit, and the predicate device, the *da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories (K182371) are regulated under the same regulation number, product code, and classification. They have the same intended use, principles of operation, and indications for use. They are identical in design except for their port systems. The subject port system (the SP Access Port Kit) and the predicate port system (SP Cannula, SP Obturator, and *EntryGuide*™ Kit) differ in device design, sterility characteristics (single-use with EO sterilization for the subject port system; reusable with steam sterilization for the predicate cannula and obturator; and single-use with gamma radiation for the predicate *EntryGuide*™ Kit), patient-contact materials (polymers and stainless steels; some same, some different), and associated software.

Performance Data

Performance test data (bench, animal, and cadaver tests) for the SP Access Port Kit demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements, user needs, and intended use. The testing is summarized below.

Design Verification Testing (Bench Testing)

The SP Access Port Kit was subjected to full design verification to specifications including:

- Physical specifications
- Mechanical requirements
- Equipment interfaces
- Reliability
- Package and labeling

The SP Access Port Kit met all the bench testing acceptance criteria, demonstrating that that the design output meets the design input requirements.

Cadaver and Animal Validations

Design validation was performed to confirm the clinical performance of the *da Vinci SP*® Surgical System, including the SP Access Port Kit, under its intended use. A complete retroperitoneal nephrectomy procedure was performed using the SP Access Port Kit in a cadaver model, and a complete transabdominal nephroureterectomy procedure was completed in a porcine model. Together, as described in **Table 1** below, design validation testing of these two procedures covers all issues of safe and effective use of the SP Access Port Kit with the *da Vinci SP*® Surgical System in the following representative urologic procedures and surgical approaches:

- Radical prostatectomy (transabdominal and extraperitoneal)
- Pyeloplasty (transabdominal)
- Nephrectomy (retroperitoneal and transabdominal)
- Partial nephrectomy (retroperitoneal and transabdominal)

Table 1: Cadaver and animal performance testing

Procedure	**Subject**	**Surgical Performance and Safety Evaluated in Procedure**
Retroperitoneal Nephrectomy	Cadaver	Assessment of the SP Access Port Kit to provide robotic and laparoscopic instrument access to the extraperitoneal space, superficial anatomy, and anatomy near bony structures.
Nephroureterectomy	Porcine	Evaluation of the ability to provide robotic and laparoscopic instrument access to a large surgical work volume (access to multiple quadrants of the body and a range of instrument depths). Assessment of instrument motion during fine dissection tasks and gross movements. Evaluation of SP Access Port Kit robustness as well as the ability of the SP Access Port Kit to maintain insufflation and remain securely installed during use.

The *da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories, including the SP Access Port Kit, met all the design validation acceptance criteria, demonstrating that it meets user needs and intended use.

Histological Evaluation

The SP Access Port Kit underwent testing to compare its effect on the port site tissue to that of the SP Cannula (predicate device, K182371) and the GelPOINT access device. (reference device, K090275) as a result of installation, incision retraction under insufflation, and removal of the port in a porcine model. Similar to the SP Access Port Kit, the GelPOINT device is used as a port to enable access of multiple instruments through a single incision for abdominal surgery. It also includes a component for wound retraction and a component for maintaining insufflation before, during, and after the insertion, use, and removal of instruments, like the SP Access Port Kit.

Also, the extent of tissue trauma at the port site and surrounding organs due to use of the SP Access Port Kit or the SP Cannula (predicate device) during completion of a left nephroureterectomy procedure with the *da Vinci SP*® Surgical System and *EndoWrist SP*™ instruments was evaluated in porcine models. For both tests, an independent pathologist evaluated the extent of tissue trauma by assessing, at a minimum, hemorrhage, necrosis and inflammation. The tissue trauma assessments were compared between devices to determine pathologically significant differences.

The pathologist concluded the following:

- There were no discernible pathologically significant differences between any of the tissue tracks examined from the SP Access Port Kit, SP Cannula (predicate device) and GelPOINT (reference device) port sites as a result of installation, incision retraction, and removal of the port.
- There were no discernible pathologically significant differences between the tissue tracks from the SP Access Port Kit and the SP Cannula used to perform a left nephroureterectomy.
- Based on gross visual examination immediately after completion of the procedures, there was no trauma to surrounding organs due to the installation, removal, incision retraction, and use of the SP Access Port Kit or SP Cannula during the surgical procedures that required further histopathological examination.
- All the samples in this study would heal normally and adequately once appropriate tissue apposition and suture closure was performed.

Clinical Validation

No clinical testing was required to support substantial equivalence.

Human Factors Evaluation

The human factors (HF) engineering process was followed in accordance with the following:

- ANSI/AAMI/IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices
- FDA, 2016, Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff

The usability risk analysis for the SP Access Port Kit was developed with feedback from internal functional group experts, using cognitive walk-through, experience from prior products, and internal testing to identify use-related risks. This usability risk analysis was updated throughout the SP Access Port Kit design process as formative testing was conducted, the design was iterated, new use errors were identified, and new mitigations were implemented. Formative testing was conducted on complete kit prototypes and on individual features of the user interface design. Those tests, along with information about the use of the *da Vinci SP*® Surgical System (Model SP1098) helped identify use-related risks for the SP Access Port Kit.

A summative validation study was conducted to evaluate high-risk use scenarios and essential tasks associated with the use of the SP Access Port Kit. This study was conducted in a simulated operating room and involved preoperative preparation and simulated surgical procedures that involved safety-critical tasks. Training materials and user manuals were developed in concert with the product and were assessed in the validation study. The goals of human factors validation testing were to:

- Validate risk mitigations to ensure use-safety and effectiveness of the SP Access Port Kit
- Assess any previously unknown use-related hazards, or identify and assess any hazards resulting from implemented mitigations
- Evaluate ease of use
- Assess effectiveness of user documentation (i.e., user manual and graphical assembly/disassembly instructions)
- Assess effectiveness of training material

A total of 16 surgical teams (surgeon and patient-side assistant) participated in the study. Surgeon participants exhibited a wide range of years in surgical practice and robotic

surgical experience. Patient-side assistants who participated in the study also varied widely in surgical experience and robotic surgical experience. Prior to the evaluation, participants underwent representative self-guided training that a user would be provided for the SP Access Port Kit. The testing sessions were conducted in a simulated operating room environment, which included overhead operating room lighting, an adjustable patient table, and accessory equipment (e.g. anesthesia equipment, energy equipment, insufflator, etc.). Participants were asked to use sterile technique within the surgical field. In addition to the normal use situation of performing the necessary tasks to complete surgical procedures, imposed scenarios were interjected to test use scenarios that may not occur during normal operation of the system. Data collected included both objective performance data and subjective feedback from participants. Objective performance data included observations of users' ability to complete tasks, use errors, close calls, and any difficulties encountered. Subjective feedback included open-ended questions about risks and safety, and follow-up interviews.

The human factors engineering process, culminating in a summative usability validation study, was used to identify and assess the use-related risks associated with the SP Access Port Kit. The safety and usability of the SP Access Port Kit were assessed to ensure that residual risk is at an acceptable level, and new hazardous use scenarios identified during testing were assessed according to an accepted risk management process and updated in the usability risk analysis for the SP Access Port Kit.

Conclusion

Based on the intended use, indications for use, technological characteristics and performance data, the Intuitive Surgical *da Vinci SP*® Surgical System, Model SP1098, *EndoWrist SP*™ Instruments, and Accessories, including the SP Access Port Kit, have been assessed and found to be substantially equivalent (SE) to the predicate devices. This SE determination is based on performance testing that included: bench testing, cadaver and animal testing with simulated and representative urologic surgical procedures, and a human factors evaluation. This testing verified and validated that the SP Access Port Kit can be used safely and effectively with the system, instruments, and other accessories, as well as with third-party laparoscopic instruments and surgical accessories, in accordance with the instructions for use to successfully complete the representative urologic surgical procedures encompassed by the indications for use statement.