September 28, 2020

Intuitive Surgical Inc.
Brandon Hansen
Regulatory Submissions Manager
1266 Kifer Road
Sunnyvale, California 94086

Re: K192717
Trade/Device Name: da Vinci SP Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 17, 2020
Received: August 18, 2020

Dear Brandon Hansen:

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 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)*
K192717

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.

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

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510(k) Summary

[As Required by 21 CFR 807.92(c)]

September 25, 2020

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Brandon Hansen
Regulatory Submissions Manager
Ph: 408-523-7485
Fax: 408-523-8907

Trade Name: *da Vinci SP®* Surgical System

Common Name: System, surgical, computer controlled instrument

Classification: Endoscope and accessories, 21 CFR 876.1500, NAY

Predicate Device: *da Vinci SP®* Surgical System (K182371)

Device Description:

The subject *da Vinci SP®* Surgical System, Model SP1098, uses advanced robotic technology to facilitate accurate movement of *EndoWrist SP™* Instruments through a single surgical port. The System includes three major subsystems (Surgeon Console, Vision Cart, Patient Cart), which are used with instruments and accessories. The system is software controlled.

There are two types of changes that are the focus of this 510(k). The first change is a modification to the Surgeon Console's FootSwitch Panel. The second change is an update to the System Software.

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 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.

Technological Characteristics: The modified da Vinci SP Surgical System is substantially equivalent to the predicate device in terms of its indications for use, design, technology and performance specifications. Modifications from the predicate device includes:

1. Hardware: The Footswitch Panel on the Surgeon Console is updated to remove the center guard dividing the control pedals and the energy pedals and removed the relocate pedal, which is now activated via the system software.

2. System Software: The modifications to the system software include changes to the user interface to allow the surgeon more control over the Erbe VIO dV ESU from the surgeon console; a new user interface activation method for the relocate mode; two new camera auto poses to control the camera control joints; a few bug fixes and other minor updates.

These modifications do not affect the substantial equivalence of the subject device to the predicate as verification and validation testing have established there are no new or different questions of safety and effectiveness.

Performance Data: Design Verification and Validation were performed on the subject device to demonstrate that the design outputs meet the design inputs and the device performs as intended. The subject device met all required specifications and functioned as intended.

Design Verification: The subject device, *da Vinci SP* Surgical System, was subjected to a series of software tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. The software design verification testing included confirmation that the device meets the user interface and software specifications.

Design Validation (animal/cadaver): The design validation testing summarized in this submission validates general, functional and interaction (compatibility) requirements for the subject device. Tests with animal model and cadaver models were performed to confirm that the subject device functions in accordance with its intended use.

Human Factors Validation: The use-safety and usability of the SP1098 Surgical System with P3 Software was validated across two studies with a mix of RASD (Robotically Assisted Surgical Device) and non-RASD experienced surgeons. Based on these two validation studies, which included analysis of participant performance and subjective data, the SP1098 Surgical System with P3 software has been determined to be substantially equivalent to the predicate for its intended uses by intended users in the intended use environment.

In this study, representative end users (participants) completed a series of intra-operative tasks designed to be representative of those performed during actual SP1098 surgical procedures. This effort assessed how various system features and functions support users while accomplishing specific tasks. This study did not assess the system's ability to deliver the intended clinical therapy. The tasks performed during the study focused on those tasks considered Critical Tasks/Primary Operating Functions (POFs) and Essential Tasks pertaining to the software modifications made to the SP1098 Surgical System with P3 Software release:

- Critical Tasks (Primary Operating Functions) - User tasks which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user.
- Essential Tasks - User tasks that are necessary to complete to ensure effectiveness of the medical device (no direct impact on safety).

The usability risk analysis was used to identify which tasks were included in this study based on the impact of the changes to use-related safety and effectiveness.

The primary objectives of this study were to ensure:

- The participants were able to use the device in a safe and effective manner (e.g., minimize use errors and the severity of resulting hazards);
- The participants were able to safely complete critical tasks; and
- The participants were able to complete essential tasks.

Additionally, this study assessed whether use-related hazards impacted by the P3 software release resulted in unacceptable residual risk to users or patients. This study also validated design mitigations / risk control measures were implemented to minimize use-related hazards that have unacceptable pre-mitigated risk levels.

A complete assessment of the study results supports the following conclusions:

- Participants are able to perform Critical Tasks (Primary Operating Functions) and Essential Tasks presented during the study, safely and effectively. All residual risks remain acceptable.
- Participant subjective feedback indicated that the use safety of the SP1098 Surgical System with P3 software is acceptable.
- There were no newly identified risks or use errors identified during the validation study that result in unacceptable residual risk (post-mitigated).

Based on the results from these validation studies with a mix of RASD and non-RASD experienced surgeons, the SP1098 Surgical System with P3 software has been determined to be substantially equivalent to the predicate device for its intended uses and by intended users in the intended use environment.

Summary: Based on the intended use, technical characteristics, and performance data, the *da Vinci SP* Surgical System with modifications is substantially equivalent to the predicate device (*da Vinci SP* Surgical System, K182371) in terms of safety, effectiveness, and performance.