



September 29, 2021

Intuitive Surgical, Inc.
Connor McCarty
Sr. Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K212747
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 26, 2021
Received: August 30, 2021

Dear Connor McCarty:

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

Indications for Use

Submission Number (if known)

K212747

Device Name

da Vinci SP Surgical System (SP1098)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

| | |
|-----------------------------|---------------------------------------|
| Applicant Name | Intuitive Surgical, Inc. |
| Applicant Address | 1266 Kifer Road Sunnyvale CA 94086 US |
| Applicant Contact Telephone | 805-798-4205 |
| Applicant Contact | Mr. Connor McCarty |
| Applicant Contact Email | connor.mccarty@intusurg.com |

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

| | |
|---------------------|--|
| Device Trade Name | da Vinci SP Surgical System (SP1098) |
| Common Name | Endoscope and accessories |
| Classification Name | System, Surgical, Computer Controlled Instrument |
| Regulation Number | 876.1500 |
| Product Code | NAY |

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|-------------|--|--------------|
| K211316 | da Vinci SP Surgical System | NAY |

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The da Vinci SP Surgical System is designed to enable complex surgery using a minimally invasive approach. The system consists of a Surgeon Console, a Vision Cart, and a Patient Cart and is used with a camera, instruments, and accessories.

The surgeon seated at the Surgeon Console controls all movement of the instruments and camera by using two hand controls and a set of foot pedals. The surgeon views the camera image on a three-dimensional (3D) viewer, which provides a view of patient anatomy and instrumentation, along with icons and other user interface features.

The Vision Cart includes supporting electronic equipment, such as the camera light source, video and image processing, and the networking hardware. The Vision Cart also has a touchscreen to view the camera image and adjust system settings.

The Patient Cart is the operative component of the da Vinci SP Surgical System. Its primary function is to support the positioning of the surgical port and to manipulate the surgical instruments and camera. The Patient Cart is positioned at the operating room table and contains an instrument arm that is positioned with respect to the target patient anatomy. The instrument arm contains four instrument drives that hold up to three surgical instruments and the camera. The patient-side assistant installs and removes the camera and instruments intra-operatively.

The subject device changes are limited to modified software, specifically modifications to the surgical instrument control algorithms. Two new functions are being added: instrument compliance compensation under load and instrument grip compensation. The instrument control algorithm changes are being made to provide more consistent performance in specific situations. There are no labeling or user interface changes associated with the enhanced instrument control algorithms.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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.

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Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are unchanged from the previously-cleared version of the system (K211316).

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The technological differences from the most recent clearance (K211316) are limited to the system software, specifically modifications to the surgical instrument control algorithms. Two new functions are being added: instrument compliance compensation under load and instrument grip compensation. The instrument control algorithm changes are being made to provide more consistent performance in specific situations.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Verification and validation testing on the subject device confirmed that no issues of safety or effectiveness and no additional unexpected risks were identified. The subject device met the same acceptance criteria as the predicate device for regression test cases. Additional new test cases within the algorithm testing verified that the new instrument control algorithm risk mitigations are effective at reducing new risks to acceptable risk levels. Therefore, the test results demonstrate that the subject device is substantially equivalent to its predicate device.