December 22, 2020

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

Re: K202968
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: September 25, 2020
Received: September 30, 2020

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

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)*
K202968

Device Name
da Vinci SP Surgical System

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

[As Required by 21 CFR 807.92(c)]

December 9, 2020

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

Official Contact: Connor McCarty
Sr. Regulatory Engineer
Phone: 805-798-4205
Fax: 408-523-8907

Trade Name: *Da Vinci SP* Surgical System

Common Name: Endoscope and accessories

Classification: System, surgical, computer controlled instrument

Predicate Device: *Da Vinci SP* Surgical System (K192717)

Reference Device: *Da Vinci Xi* Surgical System (K191529)

Device Description:

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 design modifications included in this submission are limited to updated system software, additional labeling, and additional hardware used to connect the device to a remote Intuitive server. These changes are being made to facilitate remote technical support and servicing of the device.

Indications for Use:

The indications for use are unchanged from the previously cleared version of the system (K192717).

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.

Comparison of Technological Characteristics with the Predicate Device:

The technological differences from the most recent clearance (K192717) are limited to the Vision Cart and the system software. These software and hardware changes allow the *da Vinci SP* Surgical System to communicate with a remote Intuitive server through either a wired Ethernet or wireless connection.

The purpose of the network connection to the Intuitive server is to enable the da Vinci Surgery Technical Assistance Team (DVSTAT) to remotely access system logs for pre-operative and intra-operative troubleshooting and to rapidly diagnose, and in some cases resolve, issues without dispatching a Technical Field Specialist. Additionally, remote monitoring precludes OR staff from having to relay system log information over the phone to DVSTAT, minimizing miscommunication. Remote DVSTAT users are only able to query and receive logs and diagnostic data from systems – they are not able to control or affect any of the system controls, instruments, or camera at any time.

The hardware changes are limited to two off-the-shelf networking components that are integrated into the Vision Cart: a Network Security Device (a combined firewall and gateway/router) and a Wireless Bridge. The Network Security Device provides the system with an integrated firewall which isolates the *da Vinci SP* Surgical System from the Internet and allows a hard-wired Ethernet connection to the Intuitive server over the Internet using the existing hospital network infrastructure.

As an alternative to a hard-wired connection, the Wireless Bridge allows the *da Vinci SP* Surgical System to connect to the Intuitive server over the Internet using an existing hospital wireless network. It is secured within the Vision Cart and not physically accessible by the customer.

The software changes between the predicate and subject device are limited to changes on a single existing processor within the system, the Auxiliary Video Processor (AVP) board of the Vision Cart core electronics. A new independent process running on the AVP called the DVMT embedded client will be enabled. This process will allow the system to connect and communicate with the remote server, hosted at a private Intuitive data center.

Performance Data:

The system software underwent verification testing to verify risk mitigations, requirements, and specifications related to the networking changes. Cybersecurity-related testing was conducted in alignment with the FDA Draft Guidance Document *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*[1].

The system was evaluated against standards IEC 60601-1 and IEC 60601-1-2 for safety of medical electrical equipment and EMC, respectively.

The networking hardware underwent manual bench testing to verify requirements related to the Network Security Device (a combined firewall and gateway/router) and the Wireless Bridge, including: physical installation of the router and wireless bridge, security of the ports and administrator interfaces, component dimensions, connectivity, and startup/shut down.

The addition of the Wireless Bridge to the *da Vinci SP* Surgical System was evaluated for alignment with the FDA Guidance Document *Radio Frequency Wireless Technology in Medical Devices*[2]. The system underwent wireless coexistence testing to validate the suitability of the Wireless Bridge. The system was tested in a simulated use environment that represents typical use of the system during surgery, and it was subjected to RF interference expected to be encountered in the operating room. The test article demonstrated the ability to accurately detect the instrument and endoscopes types that are used on the system under the influence of RF disturbance. No issues of safety or effectiveness and no new risks were identified.

In summary, verification and validation testing on the subject device confirmed that no issues of safety or effectiveness and no additional unexpected risks were identified, analogous to the results of the reference device verification and validation testing for networking functionality.

Conclusions:

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, K192717) in terms of safety, effectiveness, and performance.

[1] Issued on October 18, 2018

[2] Issued on August 14, 2013