May 31, 2018

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

Re: K173906
Trade/Device Name: da Vinci SP Surgical System, EndoWrist SP Instruments, and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 26, 2018
Received: April 27, 2018

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. 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 Office of Device Evaluation 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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA William H. Maisel -S

William H. Maisel, MD, MPH
Director
Office of Device Evaluation
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)*
K173906

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. 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 incision laparoscopic approach. The system is indicated for urologic surgical procedures that are appropriate for a single port approach. 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.

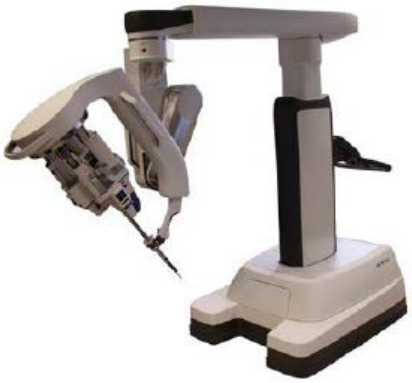
510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Elaine Lee Senior Regulatory Engineer Phone Number: 408-523-8887 Fax Number: 408-523-8907 Email: Elaine.Lee@intusurg.com
Date Summary Prepared:	May 29, 2018
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 Codes:	NAY (System, Surgical, Computer Controlled Instrument)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	*da Vinci SP* Surgical System, Model SP999, *EndoWrist SP* Instruments, and Accessories (K131962)
Reference Device:	*Intuitive Surgical da Vinci Xi* Surgical System, Model IS4000 (K131861, K152892, K161271)

Device Description

The *da Vinci SP* Surgical System, Model SP1098 is a software-controlled, electro-mechanical system designed for surgeons to perform single port minimally invasive surgery. 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.

Surgeon Console, Model SS1098



Patient Cart, Model PS1098

Vision Cart, Model VS1098

The surgeon seated at the Surgeon Console controls all movement of the *EndoWrist SP* Instruments and Camera Instrument by using two Master Controls and a set of foot pedals. The surgeon views the three-dimensional endoscopic image on a High Resolution Stereo Viewer (3D Viewer), which provides him/her a view of patient anatomy and instrumentation, along with icons and other user interface features.

The Vision Cart includes the supporting electronic and video processing equipment for the system.

The Patient Cart is positioned at the operating room table and has four instrument drives on a single arm that is positioned over the target patient anatomy. A Camera Instrument attaches onto one instrument drive and provides the surgeon a high resolution, three-dimensional view of the patient anatomy. A suite of *EndoWrist SP* Instruments can be attached to and detached from the other three instrument drives, enabling the surgeon to perform various surgical tasks. The Camera Instrument and up to three surgical instruments can be used simultaneously, entering the patient through a single port. Accessories including a cannula, an obturator, a seal, an entry guide, disposable tips for selected instruments, instrument sheaths, and a drape are needed to perform procedures with the system.

The *EndoWrist SP* Instruments come in various configurations such as graspers, scissors, and needle drivers. The *EndoWrist SP* instruments have a unique articulating design at the distal tip that mimics the human wrist, shoulder, and elbow to enable triangulation and X-Y-Z movement of the instrument in the body. Each instrument is used to perform specific surgical tasks such as grasping, suturing, tissue manipulation, and electrocautery. The *EndoWrist SP* Instruments can be used only with the SP1098 Surgical System. The instruments are reusable. They are programmed with a maximum number of surgical procedures based upon life testing.

The *EndoWrist SP* Camera Instrument is a reusable endoscope that provides a stereo image of the surgical site. Like the instruments, the distal end includes multiple joints that provide the flexibility needed for use with a single-port system.

The following *EndoWrist SP* Instruments and accessories are listed for use with the *da Vinci SP* Surgical System, Model SP1098:

EndoWrist SP Instruments:

- Fenestrated Bipolar Forceps
- Maryland Bipolar Forceps
- Medium-Large Clip Applier (a.k.a. ML Clip Applier)
- Monopolar Cautery Instrument
- Monopolar Curved Scissors (a.k.a. MCS)
- Needle Driver
- Round Tooth Retractor
- Cadiere Forceps
- *EndoWrist SP* Camera, 0° (a.k.a. Camera Instrument)

Accessories for the SP1098 *da Vinci SP* Surgical System:

- SP Cannula, Circular, 25 x 100 mm (a.k.a. Cannula)
- SP Obturator, Circular, 25 x 100 mm (a.k.a. Obturator)
- *EntryGuide* Kit C.6.6.6, 25 x 100 mm (a.k.a. Entry Guide and Cannula Seal)
- Instrument Sheath
- Camera Sheath
- MCS Tip
- Cautery Hook Tip
- Cautery Spatula Tip
- Bipolar Cautery Cord
- *EnergyShield* Monopolar Cautery Cord
- Instrument Arm Drape (a.k.a. Drape)

Intended Use:

To assist in the accurate control of endoscopic instruments in minimally invasive surgery.

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. 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 incision laparoscopic approach. The system is indicated for urologic surgical procedures that are appropriate for a single port approach. 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 *da Vinci SP* Surgical System, Model SP1098 is equivalent to the predicate device, Model SP999 (K131962), in terms of technological characteristics, and has identical indications for use. Like the Model SP999, the Model SP1098 is designed for use in single incision laparoscopic procedures.

The Model SP1098 is a modification of the Model SP999 (K131962). The Vision Cart, Surgeon Console, and Patient Cart were modified to incorporate the latest mechanical, electrical, and user interface technology of the cleared multi-port *da Vinci Xi* Surgical System, Model IS4000 (K131861, as modified by K152892 and K161271). An integrated monopolar energy monitor was also added to the Vision Cart. Modifications were also made to the *EndoWrist SP* Instruments and Accessories to improve manufacturability, robustness/reliability, cleaning ability, and ease of use while enhancing safety and maintaining the same ability to perform surgical tasks. In order to accommodate the modified instruments and to improve ease of use, the Instrument Arm and Instrument Drives were updated as well.

Attribute	**Subject Device** SP1098 *da Vinci SP* Surgical System, Instruments, and Accessories	**Predicate Device** SP999 *da Vinci SP* Surgical System, Instruments, and Accessories **(**K131962)
Device types	System Carts: • Surgeon Console • Vision Cart, including the *EnergyShield* Monitor • Patient Cart Instruments: • Fenestrated Bipolar Forceps • Maryland Bipolar Forceps • Medium-Large Clip Applier • Monopolar Cautery Instrument • Monopolar Curved Scissors • Needle Driver • Round Tooth Retractor • Cadiere Forceps Endoscope: • Camera Instrument Accessories: • Cannula • Entry Guide • Cannula Seal • Obturator • Instrument Sheath • Camera Sheath • *Energy Shield* Monopolar Cautery Cord • Drape • MCS Tip	**SAME** types of system carts as subject device. **SAME** types of available instruments and endoscope as subject device. Note: The SP999 instruments did not include a Round Tooth Retractor or Cadiere Forceps; however, the SP999 Fenestrated Bipolar Forceps is the predicate device for these new instruments. **SAME** types of accessories as subject device, plus the AEM (Active Electrode Monitor). Note: The Active Electrode Monitor and Monopolar Cautery Cord used with the SP999 system were third-party devices.
Common Name	Endoscopic instrument control system, endoscopic instruments and accessories	**SAME** as subject device

Attribute	**Subject Device** SP1098 *da Vinci SP* Surgical System, Instruments, and Accessories	**Predicate Device** SP999 *da Vinci SP* Surgical System, Instruments, and Accessories **(**K131962)
Regulation Number & Name	21 CFR 876.1500 Endoscope and Accessories	**SAME** as subject device
Classification Advisory Committee	General and Plastic Surgery	**SAME** as subject device
Product Code(s)	NAY (System, Surgical, Computer Controlled Instrument)	**SAME** as subject device
Classification	Class II	**SAME** as subject device
Intended Use	To assist in the accurate control of endoscopic instruments in minimally invasive surgery.	**SAME** as subject device
Principles of Operation	Facilitates accurate movement of surgical instruments and an endoscope through a single surgical port by using a master/slave servomechanism that incorporates servo drive and system-level motor control.	**SAME** as subject device
Prescription Use	Physician use only	**SAME** as subject device
Where Used	Hospital	**SAME** as subject device

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. The testing included dimensional measurements, mechanical and functional verification, electrical safety, and simulated use in animal and cadaver models as follows. For some components or subassemblies that are identical to those in the Model SP999 or the Model IS4000, design verification relied on previous testing.

Bench Performance Testing

The SP1098 (*da Vinci SP*) Patient Cart and subassemblies were subjected to full design verification to mechanical and electrical specifications. A summary of the design verification testing for the Patient Cart, the Instrument Arm, and the Instrument Drives is described below:

Item	Testing
Patient Cart	Brake forces Safety Lower-risk mechanical requirements Miscellaneous design features External testing
Instrument Arm	Applied loads Interfaces Mechanical design Electrical requirements Safety
Instrument Drive	Mechanical Chassis ground Reliability

The SP1098 Surgeon Console is identical to the IS4000 (*da Vinci Xi*) Surgeon Console except for modifications to the foot pedals. Verification testing was performed to confirm that the modifications meet electrical and mechanical specifications, as summarized below:

Item	Testing
Surgeon Console	Mechanical stability Cosmetic and labeling requirements
Foot Pedals	Pedal labels and layout Pedal reliability Mechanical and electrical specifications Sensors

The SP1098 Vision Cart is identical to the IS4000 Vision Cart except for the addition of the *EnergyShield* Monitor. Verification testing was performed to confirm that this modification meets electrical and mechanical specifications, and design verification testing was performed for the *EnergyShield* Monitor, as summarized below:

Item	Testing
Vision Cart	Mechanical and electrical requirements Safety
***EnergyShield*® Monitor**	Physical specifications (physical features, layout) Equipment interfaces (mechanical, electrical, cleaning) Electrical requirements Electrical safety Environmental requirements Labeling

Testing was performed on each instrument type to verify that the design meets physical, mechanical, user interface, and equipment interface requirements. A summary of the design verification testing for the SP1098 surgical instruments and camera is described below:

Item	Testing
Camera	Physical specifications (size, weight, materials) Mechanical requirements (force, range of motion, accuracy) Equipment interfaces (mechanical, electrical, cleaning, software) Electrical and patient safety Image quality Labeling
Surgical Instruments	Physical specifications (dimensions, weight, materials) Mechanical requirements (force, range of motion, accuracy) Equipment interfaces (mechanical, electrical, cleaning, software) User interface and patient safety Re-use and reliability Environmental requirements Shipping and storage Package and labeling

A summary of the design verification testing for the SP1098 accessories is described below:

Item	Testing
Cannula, Obturator, *EntryGuide*™ Kit, Instrument Sheath, Camera Sheath, MCS Tip, *EnergyShield*® Monopolar Cautery Cord, Instrument Arm Drape	Physical specifications (size, weight, materials) Mechanical and electrical requirements Equipment interfaces Re-use and reliability Package and labeling

Cadaver and Animal Performance Testing -

Cadaver models were used to demonstrate device performance for anatomical access and reach. Live animal models were used to assess safety and performance in cases where a live tissue model was appropriate. These models replicate factors experienced during use, including working with perfused organs, bleeding, normal tissue handling, and ensuring that appropriate hemostasis is achieved and maintained. Nine procedures were performed (6 cadaver, 3 porcine) to evaluate and validate the performance of the overall SP1098 system. Procedures were chosen on the basis of the types of surgical tasks that are performed, and which *EndoWrist SP* instruments are needed for the tasks.

Procedure	Subject	Performance Evaluated in Procedure
Pelvic lymphadenectomy	Cadaver	Enables evaluation of pelvic access and ability to precisely dissect around vessels.
Colectomy (Right and Left)	Cadaver	Requires access to multiple quadrants of the body, allowing evaluation of the system's range of motion and ability to work in a large work volume. Instrument and grip strength during retraction can also be assessed.
Radical Prostatectomy	Cadaver	Allows assessment of the ability to access the deep pelvis in a male model and suture in a confined space.
Pyeloplasty	Cadaver	Enables assessment of renal access and the ability to precisely suture small/thin tissues.
Total Nephrectomy	Cadaver	Enables evaluation of renal access, fine dissection ability during renal hilum dissection, and instrument strength and range of motion during mobilization of the kidney.
Partial Nephrectomy	Cadaver	Enables evaluation of fine dissection ability around vascular structures, suturing of delicate tissue, and evaluation of needle handling in a variety of orientations.
Partial nephrectomy (renal hilum dissection and clamping, specimen resection, and defect closure)	Porcine	Enables evaluation of fine dissection in live tissue and suturing of delicate tissue. Additionally, allows evaluation of needle handling in a variety of orientations.
Renal artery ligation, transection, and anastomosis	Porcine	Enables evaluation of the ability to effectively ligate blood vessels and to transect thin tissue, as well as precisely suture and manipulate small anatomy.
Bladder neck dissection, transection, and urethrovesical anastomosis	Porcine	Allows assessment of the ability to dissect deep in the pelvis as well as to transect, manipulate, and suture thick tissue. Additionally, enables evaluation of needle handling in a variety of orientations.

Three (3) independent practicing surgeons participated in a study using the SP1098 system to perform a set of urologic procedures. Each surgeon performed seven urologic procedures in a cadaver model and five representative and simulated procedures in a porcine model, for a total of 36 surgical procedures performed. The order that the procedures were performed was randomized. Success criteria for each procedure are listed below. In addition, surgeons completed questionnaires that evaluated their ability to perform surgical tasks with the SP1098 system.

Procedure	Subject	Success Criteria
Left pyeloplasty	Cadaver	Anastomosis complete and deemed acceptable upon visual inspection. Critical anatomy identified.
Right pyeloplasty	Cadaver	
Left total nephrectomy	Cadaver	Kidney completely freed from all surrounding tissues. Critical anatomy identified.
Right total nephrectomy	Cadaver	
Prostatectomy	Cadaver	Prostate is removed. Urethrovesical anastomosis is complete and deemed acceptable upon visual inspection. Critical anatomy identified.
Left pelvic lymphadenectomy	Cadaver	Lymph nodes freed from vessels. Critical anatomy identified and dissection borders achieved.
Right pelvic lymphadenectomy	Cadaver	
Pyeloplasty	Porcine	Ureter anastomosis is complete and deemed acceptable upon visual inspection. Hemostasis is maintained.
Partial nephrectomy	Porcine	2 cm diameter defect is removed. Defect is closed such that hemostasis is maintained.
Total nephrectomy	Porcine	Renal vein and artery successfully ligated. Entire kidney freed from all attachments. Hemostasis is maintained.
Bladder neck mobilization, division, and anastomosis	Porcine	3 cm length of bladder neck/urethra mobilized. Anastomosis is complete and deemed acceptable upon visual inspection. Hemostasis is maintained.
Pelvic lymphadenectomy	Porcine	Lymph node freed from surrounding tissue. Hemostasis is maintained.

Clinical Studies -

No clinical testing was provided with this submission using the subject device to support substantial equivalence.

Human Factors Performance Testing -

A 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 SP1098 usability risk analysis 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 design process as formative testing was conducted, system design was iterated, new use errors were identified, and new mitigations were implemented. Formative testing was conducted both on complete system prototypes and on individual features of the user interface design. Those tests, along with information about the use of the *da Vinci Xi* Surgical System (Model IS4000), with which the SP1098 shares some design features, helped identify use-related risks for the SP1098 system.

A summative validation study was conducted to evaluate high-risk use scenarios and essential tasks that were not assessed in previous usability validations. This study was conducted in a simulated operating room and involved preoperative preparation and simulated surgical procedures, as well as emergency procedures that involved safety-critical tasks. Training materials and user manuals were developed in concert with the product hardware and software, 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 system
- 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
- Assess effectiveness of training material

A total of 15 surgical teams (surgeon and patient-side assistant) and 15 prep teams (scrub tech and circulating nurse) participated in the study. Participants underwent the training a user would be provided for the SP1098 system on the first day. The testing sessions were conducted in a simulated operating room environment. Participants were asked to use sterile technique within the surgical field. In addition to the normal use situation of performing the necessary surgical tasks to complete the procedures, imposed scenarios were interjected to test use scenarios that may not occur during normal operation of the system, such as responding to an *EnergyShield* Monitor fault. 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, multiple choice ratings, 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 SP1098

system. The safety and usability of the SP1098 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 SP1098 system.

Consensus Standards and FDA Guidance Documents Used in Performance Testing:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- AAMI/ANSI/IEC 60601-2-2:2009, Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgery Equipment and High Frequency Surgical Accessories
- IEC 60601-2-18:2009, Medical Electrical Equipment - Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment
- IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance
- IEC 60825-1:2007, Safety of Laser Products - Part 1: Equipment Classification and Requirements
- ANSI/AAMI/IEC 62366-1:2015, Medical devices - Application of Usability Engineering to Medical Devices
- IEC 62304:2015, Medical Device Software - Software Life Cycle Processes
- AAMI/ANSI/ISO 10993-1:2009/(R)2013, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
- ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- ISO 17665-1:2006, Sterilization Of Health Care Products - Moist Heat - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- AAMI/ANSI/ISO 11137-1:2006/(R)2010, Sterilization of Health Care Products - Radiation - Part 1
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff, issued March 17, 2015.
- Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery. Guidance for Industry and Food and Drug Administration Staff, issued August 15, 2016.

- Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff, issued February 3, 2016.

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, is substantially equivalent (SE) to the predicate device. This SE determination is based on performance testing that included: bench, cadaver, and animal testing with simulated and representative urological procedures. The bench performance testing verified that the design requirements and specifications for the new and/or changed components of the system are met. The cadaver performance testing validated the users' ability to use the system to accurately control the endoscopic instruments, to reach the necessary target anatomy, and to perform surgical tasks. The simulated and representative urological procedures in live animals provided validation that the system can safely and effectively complete representative urologic procedures encompassed by the indications for use statement. Finally, the human factors assessment provided further assurance that risks due to user errors are identified and mitigated.