510(k) Summary

APR 17 2014

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
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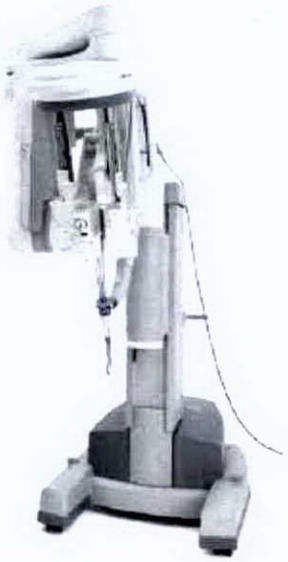
Date Summary Prepared:	April 15, 2014
Trade Name:	*da Vinci*® *Sp*™ Surgical System, Model SP999, *EndoWrist*® *Sp*™ Instruments, and Accessories
Common Name:	Endoscopic instrument control system, endoscopic instruments and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Devices:	K112208, K122532: Intuitive Surgical *da Vinci* Single-Site Instruments and Accessories K050005: Intuitive Surgical Monopolar Curved Scissors, Model 400179; Tip Cover Accessory Model 400180 K050369: Intuitive Surgical *da Vinci* Surgical System, Model IS2000 K081137: Intuitive Surgical *da Vinci Si* Surgical System, Model IS3000 K082497: Intuitive Surgical *EndoWrist One* Hot Shears Instrument K112263: Intuitive Surgical Monopolar Curved Scissors Tip Cover Accessory K123463: Intuitive Surgical *da Vinci Si* Surgical System SmartPedals

Device Description

The *da Vinci Sp* Surgical System, Model SP999 is a software-controlled, electro-mechanical system designed for surgeons to perform minimally invasive surgery. The Model SP999 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 SS999



Patient Cart, Model PS999

Vision Cart, Model VS999

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. Cleaning tools are also provided for cleaning the instruments.

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 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 SP999 Surgical System. The instruments are reusable. They are programmed with a maximum number of surgical procedures based upon life testing.

The SP999 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 SP999:

EndoWrist Sp Instruments:

- Fenestrated Bipolar Forceps
- Maryland Bipolar Forceps
- Medium-Large Clip Applier (a.k.a. ML Clip Applier)
- Monopolar Cautery
- Monopolar Curved Scissors
- Needle Driver
- Camera Instrument (a.k.a. *da Vinci Sp* Camera)

Accessories for the SP999 *da Vinci Sp* Surgical System:

- Cannula, 25 x 100 mm (a.k.a. Cannula)
- Entry Guide Kit, 25 x 100 mm (a.k.a. Entry Guide and Cannula Seal)
- Obturator, 25 x 100 mm (a.k.a. Obturator)
- Instrument Sheath
- Camera Sheath
- Monopolar Curved Scissors Tip
- Cautery Hook Tip
- Cautery Spatula Tip
- Patient Arm Drape (a.k.a. Drape)

Cleaning Accessories for the SP999 *da Vinci Sp* Surgical System:

- Water Brush, Camera
- Water Brush, Instrument
- Water Clamp, Instrument

Intended Use:

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

Indications for Use:

da Vinci® Sp™ Surgical System, Model SP999

The *Intuitive Surgical* Endoscopic Instrument Control System (*da Vinci® Sp™* Surgical System, Model SP999) 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 SP999, 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.

Technological Characteristics:

The *Intuitive Surgical da Vinci Sp* Surgical System, Model SP999 is equivalent to the predicate device, Model IS3000, in terms of technological characteristics and intended use. The SP999 is designed for single incision laparoscopic procedures similar to the IS3000 when the IS3000 was cleared with specific instrumentation in K112208 and K122532 for single incision laparoscopic procedures. The SP999 includes a new Patient Cart architecture, design and dimensional changes in the *EndoWrist Sp* Instruments and endoscope, design of a new multichannel cannula system, and modifications to the Surgeon Console foot pedals.

The predicate Patient Cart has four systems of setup joints used to position three Instrument Arms (each housing one instrument drive for an instrument) and one Camera Arm (housing one instrument drive for the endoscope). In contrast, the new Patient Cart has only one system of setup joints used to position a single Instrument Arm that houses four independent instrument drives (three for surgical instruments and one for the Camera Instrument).

The predicate *EndoWrist* instruments of the IS3000 are hinged-wrist joints. The *EndoWrist Sp* instruments have joggle joints in combination with snake-like wrist joints. This instrument design allows the instrument tip to be oriented with the same degrees of freedom as the predicate instruments. The *EndoWrist Sp* camera has the same design as the instruments, including both a wrist joint and joggle joints. The predicate endoscope is rigid, lacking any joints.

The predicate Surgeon Console has a view pedal that activates control of endoscope position and camera-focusing function. The SP999 Surgeon Console has a modified view pedal and a new arm pedal. The view pedal performs two functions, a Camera Control mode to move the articulating joints on the endoscope without movement of the instruments, and an Adjust mode to facilitate re-centering of the instruments' range of motion. The arm pedal is used to re-orient the instruments and camera as a group, pivoting around the single port. This mode (Relocate mode) can be used to move the instruments and camera to a different surgical quadrant.

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.

Bench Verifications -
The SP999 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 (or Entry Guide Manipulator, EGM), and the Instrument Drives is described below:

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

The SP999 Surgeon Console has many of the same functional requirements as the IS3000 Surgeon Console. The main hardware modification to the SP999 Surgeon Console is to the foot

pedals. Verification testing was performed to confirm that the modifications meet electrical and mechanical specifications.

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

Engineering design verification was performed on the SP999 Vision Cart and the SP999 Camera Control Unit (CCU). A summary of the design verification testing for the Vision Cart and CCU is described here:

Vision Cart	Mechanical and electrical requirements Safety and reliability Labeling and cleanability
Camera Control Unit (CCU)	Camera interface Camera control and video processing Vision Cart compatibility Safety and reliability Noise level Mechanical and electrical requirements Labeling and cleanability

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 SP999 surgical instruments and camera is described below:

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 SP999 accessories is described below:

Accessories Including Cannula, Obturator, Entry Guide, Instrument Sheath, Camera Sheath, Tip Covers, Drapes	Physical specifications (size, weight, materials) Mechanical and electrical requirements Equipment interfaces Re-use and reliability Labeling and packaging

Cadaver and Animal Validations -

Cadaver models were used to demonstrate clinical 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 clinical use, including working with perfused organs, bleeding, normal tissue handling, and ensure that appropriate hemostasis is achieved and maintained. Eleven procedures were performed (5 cadaver, 6 porcine) to evaluate and validate the performance of the overall SP999 system (sample size = 1). Procedures were chosen on the basis of the types of surgical tasks that are performed, and which *EndoWrist* instruments are needed for the tasks. These procedures were performed by clinical development engineers:

Procedure	Subject	Surgical Tasks Evaluated in Procedure
Pelvic lymphadenectomy	Cadaver	Enables evaluation of pelvic access and ability to precisely dissect around vessels.
Colectomy	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.
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.
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.
Renal hilum dissection & renal artery anastomosis	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 & vein ligation/ transection	Porcine	Enables evaluation of the ability to effectively ligate blood vessels and to transect thin tissue.
Ureter dissection, transection, & anastomosis	Porcine	Enables assessment of the ability to dissect and transect live tissue, as well as precisely suture and manipulate small anatomy.
Cystic artery & duct dissection	Porcine	Enables evaluation of precise dissection and safe grasping of live tissue.
Bladder neck dissection, transection, & 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.

Bladder and uterine horn amputation and closure	Porcine	Enables evaluation of the ability to transect, manipulate, and suture thick tissue.

For comparison to the predicate, five (5) independent practicing surgeons participated in a study completing a comprehensive set of urologic surgical procedures using both the SP999 (subject) and the IS3000. With each system, each surgeon performed seven urologic procedures in a cadaver model and six representative procedure steps in a porcine model, for a total of 65 surgical procedures performed with each system. The order that the procedures were performed was randomized. Success criteria for each procedure are listed in Table 2. In addition, surgeons completed questionnaires that evaluated their ability to perform surgical tasks with the two systems.

Procedure	**Subject**	**Surgical Tasks Evaluated in Procedure**
Left pyeloplasty	Cadaver	During a pyeloplasty, the surgeon requires access to the ureter and renal hilum and requires precise control of instruments to effectively suture the anastomosis. **Success Criteria:** Anastomosis complete with no visible gaps where leaking could occur
Right pyeloplasty	Cadaver	
Left total nephrectomy	Cadaver	During a nephrectomy, the surgeon requires sufficient range of motion to circumferentially dissect the kidney and needs precise control of instruments to safely dissect around blood vessels. **Success Criteria:** Kidney completely freed from all surrounding tissues
Right total nephrectomy	Cadaver	
Prostatectomy	Cadaver	During a radical prostatectomy, the surgeon accesses a broad range of anatomy from the urachus to the distal urethra, deep in the pelvis. In addition, removing the lymph nodes requires access to the right and left pelvic walls. The surgeon also requires precise control of instruments to enable safe dissection around blood vessels and effective suturing. **Success Criteria:** Prostate completely removed, no leaking of anastomosis when bladder is filled with water (~120mL)
Left pelvic lymphadenectomy	Cadaver	**Success Criteria:** Lymph nodes freed from vessels, anatomic landmarks to define dissection boundaries visualized
Right pelvic lymphadenectomy	Cadaver	
Ureter skeletonization, transection, and anastomosis (Pyeloplasty)	Porcine	**Success Criteria:** Anastomosis complete with no visible leaks of urine
Renal hilum dissection	Porcine	**Success Criteria:** Renal artery and renal vein sufficiently dissected to enable ligation
Partial nephrectomy	Porcine	**Success Criteria:** Defect closed such that hemostasis is maintained following removal of the Bulldog clamp
Total nephrectomy	Porcine	**Success Criteria:** No blood leaks following ligation of the renal artery and renal vein, entire kidney freed from all attachments
Bladder neck mobilization, division, and anastomosis	Porcine	**Success Criteria:** No leaking from anastomosis when bladder filled with water (~100-120mL or until full)
Pelvic lymphadenectomy	Porcine	**Success Criteria:** Lymph node freed from surrounding tissue

Clinical Validation -
No clinical testing was provided with this submission using the subject device.

Human Factors Evaluation -
A human factors (HF) engineering process was followed in accordance with FDA guidelines for medical devices:

- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, 2000
- Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011

The SP999 Human Factors Hazard 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 human factors hazard 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 previous *da Vinci* Surgical Systems (Models IS1200, IS2000, and IS3000), helped identify use-related risks for the SP999 system. Additionally, an earlier version of the SP999 was used in a clinical investigation, which provided valuable usability feedback that led to the current design iteration.

A summative validation study conducted with 15 teams of users (surgeons and patient side assistants). This study was conducted in a simulated OR 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 (i.e., User Manual and Instructions for Use)
- Assess effectiveness of training material

A total of 15 user teams participated in the study, each team consisting of a surgical urologist and a patient side assistant. Surgeon participants exhibited a wide range of age (34 – 65 years), years in surgical practice (2 - 30 years), and robotic surgical experience (13 – 1000 cases). Patient side

assistants also varied in age (26 – 52 years), experience (55 – 40,000 cases), and robotic patient side experience (0 – 9000 cases). Participants underwent the training a user would be provided for the SP999 system on the first day. 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 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 a non-recoverable system 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 SP999 has been assessed and found to be safe and effective for its intended uses, by the intended users, in its intended use environment. The human factors engineering process, culminating in a usability validation study, was used to identify and assess the use-related risks associated with the SP999. The safety and usability of the SP999 were assessed to ensure residual risk is at acceptable levels, and that new hazardous use scenarios identified during testing were assessed according to an accepted risk management process and updated in the Human Factor Hazard Analysis for the SP999.

Feasibility Study

The 510(k) also included information with thirty (30) day post-operative outcomes on 19 human clinical cases (11 prostatectomies, 4 nephrectomies, 4 partial nephrectomies) successfully performed with a functionally equivalent prototype version of the SP999 system as part of an OUS feasibility study. The clinical data were not used to demonstrate substantial equivalence to the predicate device, but served to supplement the animal and cadaver testing and provided further evidence that the new design of the SP999 is safe and effective in a human clinical setting.

Conclusion:

Based on the intended use, indications for use, technological characteristics and performance data, the *Intuitive Surgical da Vinci® Sp™* Surgical System, Model SP999, *EndoWrist Sp™* Instruments, and Accessories, is substantially equivalent (SE) to the predicate devices. This SE determination is based on bench testing including reliability testing, animal/cadaver validation, simulated clinical procedures in live animals, and human factors assessment. The bench/reliability testing verified that the design requirements and specifications for the new and/or changed components of the system are met. The animal/cadaver validation demonstrated 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 clinical procedures in

live animals provided clinical validation that the system can safely and effectively complete representative surgical 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.

This SE determination did not require clinical data for the following reasons:

- The indications for use are within the scope of the predicate device (*da Vinci* IS3000).
- The changes to the device hardware and software were such that bench testing, animal/cadaver validation, and simulated clinical procedures in live animal were adequate to establish SE to the predicate.

This review did not compare human clinical performance between the *da Vinci® Sp™* Surgical System, Model SP999, *EndoWrist Sp™* Instruments, and Accessories and its predicates. This review did not assess user training although a training program was described as part of the human factors assessment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Intuitive Surgical Incorporated
Mr. Mike Yramategui
Principal Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K131962
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: March 14, 2014
Received: March 18, 2014

Dear Mr. Yramategui:

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). 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 (SP999).

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.

If you desire specific advice for your device on our labeling regulation (Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy L. Foreman -S

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

510(k) Number if known: K131962

Device Name: SP999 *da Vinci® Sp™* Surgical System

INDICATIONS FOR USE:

da Vinci® Sp™ Surgical System, Model SP999

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci® Sp™* Surgical System, Model SP999) 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 SP999, 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.

Prescription Use _X_ AND/OR Over-the-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S