K131861

510(k) Summary

MAR 2 8 2014

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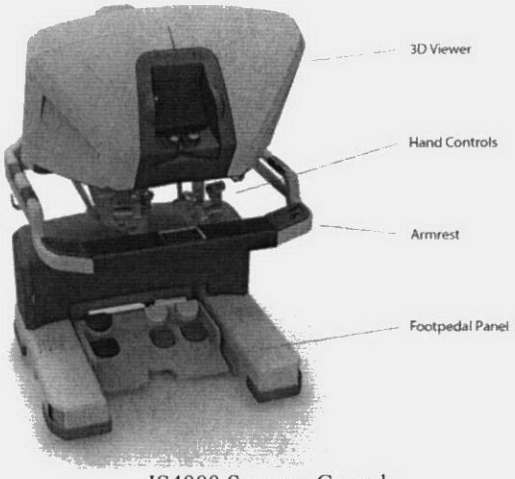
Date Summary Prepared:	March 26, 2014
Trade Name:	*da Vinci*® Surgical System, Model IS4000
Common Name:	Endoscopic instrument control system, endoscopic instruments and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument) GCJ (Laparoscope, General & Plastic Surgery)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	Intuitive Surgical *da Vinci*® *Si* Surgical System, Model IS3000 (K081137, K090993, K123463)

Device Description

The *da Vinci* Surgical System, Model IS4000 is a software-controlled, electro-mechanical system designed for surgeons to perform minimally invasive surgery. The Model IS4000 Surgical System consists of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and is used with an Endoscope, *EndoWrist* Instruments, and Accessories.

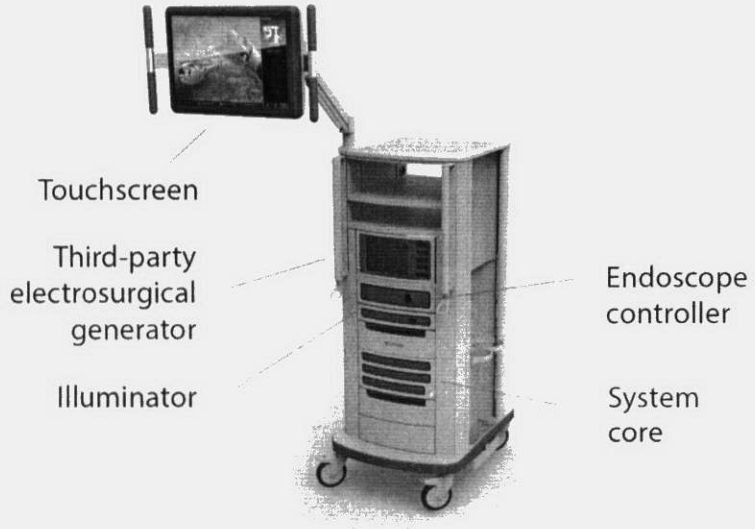
The surgeon seated at the Surgeon Console controls all movement of the *EndoWrist* Instruments and Endoscope by using two Master Controls and a set of foot pedals. The surgeon views the three-dimensional endoscopic image on a High Resolution Stereo

Viewer (3D Viewer), which provides him/her a view of patient anatomy and instrumentation, along with icons and other user interface features.



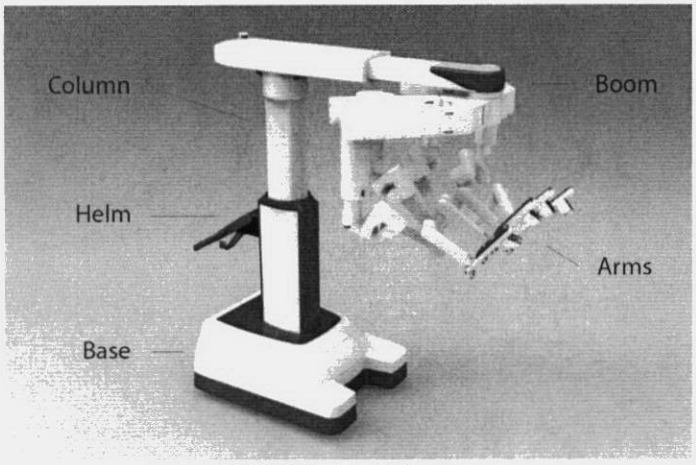
IS4000 Surgeon Console

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



IS4000 Vision Side Cart

The PSC is positioned at the operating room table and has four endoscope/instrument arms that are positioned over the target patient anatomy. An endoscope attaches onto one arm and provides the surgeon a high resolution, three-dimensional view of the patient anatomy. A suite of *EndoWrist* Instruments are attached/detached from the arms, enabling the surgeon to perform various surgical tasks. Accessories such as cannulas, obturators, seals, and drapes are also needed to perform procedures with the system.



IS4000 Patient Side Cart

The IS4000 Endoscope is a multi-use device that comprises a 3D camera in a light-weight design (60% lighter as compared to IS3000). The Endoscope can be used laparoscopically (hand-held) at the start of a surgery and then be installed on any arm of the PSC.

The *EndoWrist* Instruments come in various configurations such as Graspers, Scissors, and Needle-drivers. A total of 24 8 mm *EndoWrist* Instruments for the IS4000 are listed in **Table 1**:

Table 1: *EndoWrist* Instruments for the IS4000

Monopolar Curved Scissors	Permanent Monopolar Cautery Hook	Permanent Monopolar Cautery Spatula
Maryland Bipolar Forceps	Fenestrated Bipolar Forceps	Curved Bipolar Dissector
Micro Bipolar Forceps	Large Needle Driver	Mega SutureCut Needle Driver
Black Diamond Micro Forceps	ProGrasp Forceps	Tenaculum Forceps
Tip-Up Fenestrated Grasper	Resano Forceps	Small Grasping Retractor
Long Tip Forceps	Cardiac Probe Grasper	Large Hem-O-Lok Clip Applier
Medium Hem-O-Lok Clip Applier	Small Clip Applier	Dual Blade Retractor

Atrial Retractor Short Right	Snap-Fit Instrument	Potts Scissors

The *EndoWrist* instruments have a unique articulating design at the distal tip that mimics the human wrist. Each instrument is used to perform a specific surgical task such as grasping, suturing, tissue manipulation and electrocautery. The IS4000 *EndoWrist* Instruments can only be used with the IS4000 Surgical System. The instruments are reusable. They are programmed with a maximum number of surgical procedures based upon life testing. This is identical to the IS3000 instruments.

A number of accessories are required to perform minimally invasive surgery with the IS4000 System including cannulas, obturators, and sterile drapes. Some accessories are modified to interface with the updated IS4000 System and instruments, while others are identical to the accessories used with the predicate IS3000 System. The complete list of IS4000 accessories is listed in **Table 2**:

Table 2: IS4000 Accessories

8 mm Cannula (standard and long)	8 mm Flared Cannula
8 mm Blunt Obturator (standard and long)	8 mm Instrument Introducer
Arm and Column Drape	Instrument Release Kit
Endoscope Sterilization Tray	Tip Cover Accessory (for Monopolar Curved Scissors)
SnapFit Scalpel Blade and Paddle Blade	SnapFit Insertion Tool (reusable)
5-8 mm Cannula Seal	Gage Pin

Intended Use:

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

Indications for Use:

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, 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, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures,

gynecologic laparoscopic surgical procedures. general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used 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* Surgical System, Model IS4000 is equivalent to the predicate device, Model IS3000, in terms of technological characteristics and intended use. Modifications to the IS3000 include an updated Patient Side Cart architecture, design and dimensional changes to the *EndoWrist* Instruments and endoscope, and updated user interfaces.

Performance Data:

Performance test data to support substantial equivalence to the predicate device and that the design output meets the design input requirements consist of bench testing, animal/cadaver validation, simulated clinical procedures in live animal, and Human Factor assessment.

Bench Verification

The bench testing conducted consisted of dimensional measurements, mechanical and functional verification, electrical safety, and reliability. For the IS4000, the Surgeon Console was not subjected to any bench testing since there was no change made to the hardware. Changes were made to the software, graphical user interface, and cosmetic changes that were tested as part of the overall system. The suites of bench tests are:

Test	Summary
Design Verification - PSC	The purpose of these tests was to verify that the physical, mechanical, electrical, and system level requirements and design specifications were met for each sub-component of the PSC. Sample size varied from 1 to 6 units depending on the test case. Test methods were based on pre-defined test procedures. Objective pass/fail criteria are defined and used. The following PSC sub-components were tested: • Cart Drive • Set-up Structure (SUS) • Set-up Joint (SUJ) • Universal Surgical Manipulator (USM) • PSC Overload Testing

Test	Summary
	• Audio Intercom Hardware
Design Verification - VSC	The purpose of these tests was to verify the sub-components of the VSC met the functional requirements as defined in the applicable Functional Specification Documents. Sample size was 1 unit except for the Endoscope and Endoscope adapter where 4 to 5 units were tested. Test methods were based on pre-defined test procedures. Objective pass/fail criteria were defined and used. The following VSC sub-components were tested: • Video Processor hardware • Endoscope Controller hardware • 8.5 mm Endoscope • Endoscope adapter
Instrument Design Verification	The purpose of these tests was to verify the IS4000 instruments met the physical, mechanical, and electrical requirement and specifications. Instrument compatibility to software parameters and user interface specifications were also verified. Samples sizes up to 5 units for all 24 instruments were used. For load handling and grip forces verification, worst case representative instruments were tested. The following design verification tests were performed: • All Instrument types (24) • Instrument Electrical Testing • Load Handling • Grip Force Comparison for grasping instruments

Test	Summary
Instrument Reliability/Life Testing	The purpose of this test was to confirm the instruments met the projected life of each re-usable instrument. A sample of 9 instruments types was subjected to life testing representing worst case for all 24 instruments. A sample size of 4 units of each type was tested. Test instruments were tested up to 8 life cycles to establish a projected life of 5 clinical uses. Each life cycle consisted of cleaning, sterilizing, performance measurements, and simulated surgical use. Objective pass/fail criteria were defined and used. The following instruments were evaluated: • Monopolar Curved Scissors • Maryland Bipolar Forceps • Large Needle Driver • Black Diamond Micro Forceps • Mega SutureCut Needle Driver • ProGrasp Forceps • Tenaculum Forceps • Permanent Cautery Hook • Small Clip Applier
Accessories Testing	• The purpose of this test was to confirm that Column and Instrument Arm Drapes with sterile adapters met the specifications and requirements for maintenance of sterility. A sample of 5 units of each type was evaluated per the verification protocol. Objective pass fail criteria were defined and used. • Reusable trocars were tested for physical, mechanical, and interface requirements. A sample of 4 units of each type of reusable trocar was tested per the verification protocol. Objective pass/fail criteria were defined and used.

Pre-Clinical Verification via cadaver and animal models

The IS4000 system was evaluated for surgical access for seven representative procedures using multiple patient positions and port locations involving 10 cadavers (2 male and 8 female) and one 20 kg porcine model. Test cases validated requirements across all system components associated with system set-up, positioning, docking, transporting and procedure specific requirements for achieving external access and internal surgical

targets. Specifically, the protocol focused on the IS4000 system's ability to safely and effectively:

- Maneuver the PSC and USMs into proper surgical position for the target procedure
- Reach and attach the USMs to the ports
- Maintain adequate external clearance between the system and its surroundings at all times (e.g., during transport, roll-up, and intraoperative use)
- Reach the internal surgical targets with the instruments and endoscope
- Maximize patient access

The following table shows the types of procedures used to set-up and deploy the system:

Procedure/ # of cases	Port Location	Port Spacing	Work Volume	Body Wall Type	Patient Position	Working Distance
Low Anterior Resection/ 2 (cadaver)	Anterior Transverse/ Anterior Oblique	8-11 cm	> 3k cm^3	Abdomen	Trendelenburg Right roll Lithotomy	3-15 cm
Gastric Bypass/ 3 (cadaver)	Anterior Transverse	8-11 cm	Between 1-3k cm^3	Thick Abdomen	Reverse Trendelenburg Lithotomy	4-12 cm
Hysterectomy/ 3 (cadaver)	Anterior Transverse	8-11 cm	> 3k cm^3	Abdomen	Trendelenburg Lithotomy	3-15 cm
Mitral Valve Repair/ 1 (cadaver)	Lateral, Anterior, Coronal	2-8 cm	<1k cm^3	Ribs	Supine, Left roll right arm down	2-8 cm
Cardiac Revascularization/ 1 (cadaver)	Lateral, Anterior, Coronal	5-8 cm	Between 1-3k cm^3	Ribs	Supine, drop Left shoulder	2-8 cm
Nephrectomy w/ partial Ureterectomy/ 3 (cadaver)	Anterior, Lateral, Sagittal	5-11 cm	Between 1-3k cm^3	Abdomen	Lateral decubitus, flex	2-9 cm
Pediatric/ 2 (small porcine <20 kg)	Variable	2-5 cm	Between 1-3k cm^3	Abdomen	Variable	2-10 cm

Representative Surgical Procedures in Live Animal Models

A series of six evaluations in which surgeons performed complete procedures on live animal models were conducted covering the range of specialties listed in the indication statement. Each study included clinical endpoints to assess safety and effectiveness of the IS4000 system that were appropriate for the procedure being performed. The evaluations for five of the six specialties involved surviving the animal models for a minimum of 21 days.

General laparoscopic surgical procedures

Right Colectomy Prospective Study	**Canine Model (N=4) with weights 25-35 kg**
No. of Investigators:	One (trained on system 4-6 weeks prior to use)
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during post-op period.
Success Criteria Effectiveness:	Ileocolic anastomosis intact and looking healthy at day of euthanasia. Normal eating and bowel movements over post-op period.
Instrumentation Used:	Fenestrated Bipolar Forceps, Tip-Up Grasper, 30° down endoscope, Monopolar Curved Scissors, EndoGIA® Ultra-Universal stapler, Endopouch® specimen retrieval bag, and LigaClips.
Findings:	1. Surgical time ranged from 30-65 minutes shorter times noted with each subsequent case. 2. There was no conversion to open surgery. 3. Estimated blood loss was 10 ml in all cases.
Adverse Events:	1. Unanticipated splenic injury with placement of port. Splenic injury was repaired and procedure continued without further incident. 2. There were no device-related adverse events.
Postmortem Assessment Protocol:	1. Animals were euthanized and the operative site examined grossly for intactness of the ileoclic anastomosis and tissue health. 2. Blood samples collected for hematology and chemistry analysis. 3. Histopathology if needed on abnormal tissue as determined by Veterinary Pathologist.
Postmortem findings:	1. All four animals survived for 26 days with normal vital signs and absence of device-related adverse events intra-operatively and during the post-operative period. 2. One animal presented with intermittent inappetance, moderate weight loss and clinical pathology results indicative of ongoing inflammation. 3. The ileocolic anastomoses were intact and functional at the end of the survival period. In the animal with irregular clinical observations, solid feces were found distal to the anastomosis with surrounding tissue inflammation (not device-related) at the end of the survival period. 4. All animals had a loop of small bowel covering the staple line, as observed during the post-survival evaluation surgery. This did not cause obstruction of the anastomosis in any of the animals. All other animals were free of clinically significant variances in observations or clinical pathology.

General laparoscopic surgical procedures (pediatric)

Nissen Fundoplication Prospective Study	**Canine Model (N=4) with weights 9-15 kg (representative of pediatric population)**
No. of Investigators:	One
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during postoperative period.
Success Criteria Effectiveness:	Fundoplication wrap intact and looking healthy at day of euthanasia. Normal eating over post-op period.
Instrumentation Used:	Monopolar Curved Scissors , Fenestrated Bipolar Grasper, Tip-Up Grasper, 30° down endoscope, Large Needle Drivers
Findings:	1. Surgery time ranged from 48–68 min. 2. No animal required conversion to open surgery. 3. Estimated blood loss average was 13.8 ml. 4. Moderate weight loss occurred in all four animals during the course of the study, and ranged from a 1.1-1.7 kg decrease. 5. All animals retained good appetites and were clinically healthy throughout the duration of the survival period with no observations of vomiting, regurgitation, or other GI upset, and no reported loss of body condition. The weight loss was likely due to decreased caloric intake as a result of the post-operative dietary change to canned food/gruel to accommodate GI tract changes from the Nissen fundoplication.
Adverse Events:	1. One animal sustained a splenic injury during takedown of the gastro-colic ligament using the Monopolar Curved Scissors. Bleeding was controlled by applying standard surgical techniques of pressure to the puncture site with a 4x4 gauze and monopolar electro-cautery. Hemostasis was achieved and this event had no impact on the clinical outcome for the animal. This was felt to be related to surgical error rather than instrumentation as the scissor was under the command of the surgeon and not a result of motions from the system.
Postmortem Assessment Protocol:	1. Animals were euthanized and the operative site examined grossly for intactness of fundal wrap and tissue health. 2. Blood samples collected for hematology and chemistry analysis. 3. Histopathology if needed on abnormal tissue as determined by Veterinary Pathologist.
Postmortem Findings:	1. In the post-survival evaluation surgeries on Day 24, all wraps were found to be intact with no abnormalities noted in the surrounding tissue. 2. One slight adhesion was noted at a port site in one animal.

General urologic surgical procedures (pediatric)

Pyeloplasty Prospective Study	**Porcine Model (N=4) with weights 25-30 kg**
No. of Investigators:	One
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intra-operative and post-op periods.
Success Criteria Effectiveness:	Normal passage of urine throughout the survival period. Normal peristalsis of ureter at day of euthanasia. No stricture of ureter at day of euthanasia. Normal eating and bowel movements over post-op period.
Instrumentation Used:	Tip Up Grasper, Monopolar Curved Scissors, Maryland Bipolar Forceps, Large Needle Driver
Findings:	1. Surgical time range from 50-62 minutes. 2. There were no conversions to an open procedure. 3. Estimated blood loss average was 15 ml.
Adverse Events:	1. One animal was noted to have thickened port sites with some purulent material expressed. Peritoneal wounds on this animal had healed normally. 2. There were no device-related adverse events.
Postmortem Assessment Protocol:	1. Animals were euthanized and the operative site examined grossly for intactness of the pyeloplasty, presence or absence of intra-peritoneal fluid, peristaltic activity. 2. Blood samples collected for hematology and chemistry analysis. 3. The anastomotic segment was explanted and histopathology performed by Veterinary Pathologist.
Postmortem Findings:	1. All four animals survived for 26 days with normal vital signs and absence of device-related adverse events intra-operatively and during the post-operative period. All animals were free of clinically significant variances in observations or clinical pathology. 2. The ureteral anastomoses were intact and functional at the end of the survival period. There was no evidence of stricture as evidenced by the successful passage of a 6F dilator. 3. All animals were found to have 20cc clear abdominal fluid at euthanasia. This was the same finding prior to beginning the surgery.

Urologic surgical procedures

Radical Nephrectomy Prospective Study	**Female Porcine Model (N=4) with weights 50-60 kg**
No. of Investigators:	One (trained on system 6 weeks prior to study)
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intra-operative and post-op periods.
Success Criteria Effectiveness:	Successful organ removal. Normal eating and bowel movements over post-op period

Instrumentation Used:	Tip Up Grasper, Monopolar Curved Scissors, Fenestrated Bipolar Forceps, Laparoscopic EndoGIA Ultra-Universal stapler,
Findings:	1. Surgical time range from 35-42 minutes. 2. There were no conversions to an open procedure. 3. Successful removal of kidney in all animals. 4. Estimated blood loss average 12.5ml.
Adverse Events:	1. One splenic injury during port placement controlled with local measures. 2. There were no device-related adverse events.
Postmortem Assessment Protocol:	1. Animals were sedated and the operative site palpated for pain and swelling and then euthanized. All port sites healed. 2. Blood samples collected for hematology and chemistry analysis. 3. Histopathology performed by Veterinary Pathologist on abnormal tissue if needed.
Postmortem Findings:	1. All four animals survived for 25-28 days with normal vital signs and absence of device-related adverse events intra-operatively and during the post-operative period. 2. No inappetance or other GI disturbances were reported, and all animals remained in good condition throughout the duration of the survival period. 3. None of the animals showed any signs of pain reaction.

Gynecologic laparoscopic surgical procedures

Hysterectomy Prospective Study	**Female Porcine Model (N=4) with weights 35-40 kg**
No. of Investigators:	One (trained on system 2 weeks prior to study)
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intra-operative and post-op periods.
Success Criteria Effectiveness:	Successful organ removal. Normal eating and bowel movements over post-op period.
Instrumentation Used:	Tip Up Grasper, Monopolar Curved Scissors, Fenestrated Bipolar Forceps, Mega SutureCut Needle Driver,
Findings:	1. Surgical time range from 29-55 minutes; shorter time noted with each subsequent case. 2. There was no conversion to an open procedure. 3. Estimated blood loss average 10ml. 4. Successful removal of uterus in all animals.
Adverse Events:	There were no device-related adverse events.
Postmortem Assessment Protocol:	1. Animals were euthanized and the vaginal cuff closure assessed. A trans-vaginal leak test was performed. 2. Blood samples collected for hematology and chemistry analysis. 3. Histopathology performed by Veterinary Pathologist on abnormal tissue if needed.

Postmortem Findings:	1. All four animals survived for 21 days with normal vital signs and absence of device-related adverse events intra-operatively and during the post-operative period. 2. All vaginal cuffs were found to be intact with no abnormalities noted in the surrounding tissue. 3. There were no leaks observed in the trans-vaginal air leak testing.

General thoracoscopic surgical and thoracoscopically-assisted cardiotomy procedures

Mitral Valve Repair Prospective Study	**Canine Model (N=9[a]) with weights 28-35 kg Comparative performance study of da Vinci IS3000 to the IS4000**
No. of Investigators:	Two board certified cardio-thoracic surgeons each performed 4 procedures, 2 using the IS3000 and 2 using the IS4000.
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events.
Success Criteria Effectiveness:	1. Placing a cardioplegia catheter. 2. Simulating pacemaker lead placement. 3. Closing a leaflet defect. 4. Perform an annuloplasty with a flexible band. 5. Intra-operative valve leak test as surrogate for assessment of mitral regurgitation.
Instrumentation Used:	Large Needle Driver, Resano Forceps, Atrial Retractor Short Right, Monopolar Curved Scissors
Procedural Steps:	1. Placing a cardioplegia catheter. 2. Simulating pacemaker lead placement. 3. Closing a leaflet defect. 4. Perform an annuloplasty with a flexible band.
Findings:	1. Total surgical time for all steps was 67-93 minutes for the IS3000 and 76-101 minutes for the IS4000. 2. Time to cardioplegia catheter averaged 8.71 minutes for the IS3000 and 8.12 minutes for the IS4000. 3. Time for lead placement averaged 13.25 minutes for the IS3000 and 13.5 minutes for the IS4000. 4. Time to completion of annuloplasty averaged 14.74 minutes for the IS3000 and 14.57 minutes for the IS4000. 5. All animals had measures for mitral valve regurgitation that were equal to pre-operative measures. All changes were acceptable to surgeons.
Adverse Events:	[a]One animal (D955) in the IS4000 group died intra-operatively due to a non-device-related adverse event, an acute onset pulmonary complication leading to bronchial obstruction with reduced O_2 exchange. This animal was excluded from the study, and another animal (D999) added to the study. There were no device-related adverse events.
Postmortem Assessment Protocol:	None as animals were euthanized during the procedures to simulate bypass machine.

The results of the animal testing demonstrate that the IS4000 Surgical System can be used to safely and effectively perform procedures from all of the specialties listed in the indications for use statement.

Human Factors

A Human Factor (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 HF process focused primarily on identifying and mitigating use-related risks to safe levels while also providing a user friendly product. For the IS4000 system, an extensive HF process was followed documenting many user research, design iteration, and formative evaluations prior to usability validation testing. A summative usability validation study was conducted with 15 teams of users (surgeons and OR team). This study was conducted in a simulated OR and involved representative typical workflow scenarios as well as troubleshooting scenarios that involved safety-critical tasks. Training materials and user manuals were developed in concert with the product hardware and software, and were incorporated in the validation study. The study assessed the following:

- ensure intended users could perform essential and high risk tasks in the expected use environments in a safe and effective manner;
- validate that use-related risks have been mitigated to acceptable levels of residual risk;
- assess the overall ease of use and usability of the IS4000 Surgical System;
- this study evaluated whether the design introduced any previously unknown use-related risks.

Fifteen surgeons from different surgical specialties (urology, gynecology, general surgery and thoracic) from novice (<20 cases) to very experienced (>200 cases) participated in the study. In addition, fifteen OR staff (5 circulating nurses, 9 scrub nurse/tech, and 1 physician's assistant) provided OR support during the sixteen study sessions. Each participant received one-half day of hands-on training prior to conducting testing. A simulated OR environment was provided to perform pre-operation set-up tasks (e.g., docking, draping, power on), intraoperative tasks (e.g., installing and activating instruments, instrument exchange, manipulating instruments), and post-operative tasks (e.g., undocking, cleaning, sorting for reprocessing). 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 Model IS4000 *da Vinci* Surgical System 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 Factor engineering process, culminating in a usability validation study, was to identify and assess the use-related risks associated with the IS4000 Surgical System. The safety and usability of the IS4000 Surgical System was assessed to ensure residual risk is at acceptable levels, and that the use-safety of the system has not diminished in comparison to the IS3000 Surgical System.

Summary:
Based on the intended use, indications for use, technological characteristics and performance data, the Intuitive Surgical *da Vinci* Surgical System, Model IS4000, is substantially equivalent (SE) to the predicate device, the Intuitive Surgical *da Vinci Si* Surgical System, Model IS3000. 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 animals were adequate to establish SE to the predicate.

This review did not compare human clinical performance between the IS4000 System to the IS3000 System. This review did not assess user training, although a training program was described as part of the human factors assessment. Finally, because there were no human clinical data, user learning curve was not assessed for the new model.

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

March 28, 2014

Intuitive Surgical Incorporated
Mr. Brandon Hansen
Senior Manager, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K131861
Trade/Device Name: da Vinci Surgical System, Model IS4000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: June 19, 2014
Received: June 24, 2013

Dear Mr. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

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 (21 CFR 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" (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.

You may obtain other general information on your responsibilities under the Act from 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.

Sincerely yours,

Binita S. Ashar -S
2014.03.28 16:00:30 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
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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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131861

Device Name
da Vinci Surgical System, Model IS4000, and EndoWrist® Instruments, and Accessories

Indications for Use *(Describe)*

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, 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, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Long H. Chen -A for BSA

(Division Sign-Off)

Division of Surgical Devices

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