March 14, 2019

Intuitive Surgical, Inc.
Mike Yramategui
Fellow Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K182371
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: February 11, 2019
Received: February 12, 2019

Dear Mike 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

The 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 and for transoral otolaryngology surgical procedures in the oropharynx for benign tumors and malignant tumors classified as T1 and T2 with the da Vinci EndoWrist SP Instruments and the da Vinci SP Surgical System (SP1098).

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Angela C. Krueger -S for

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)*

K182371

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 and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

EndoWrist SP ® Instruments:
Intuitive Surgical® *EndoWrist SP* ® Instruments are controlled by the *da Vinci SP*® Surgical System, Model SP1098, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. The system is indicated for urologic surgical procedures that are appropriate for a single port approach and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

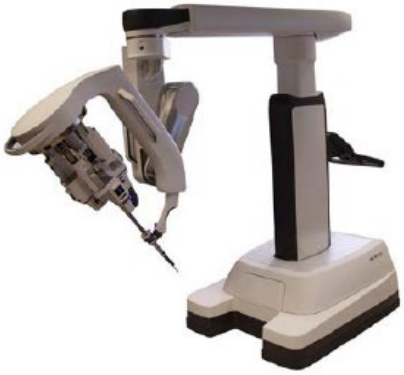
510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Mike Yramategui Fellow Regulatory Engineer Phone Number: 408-523-2145 Fax Number: 408-523-8907 Email: Mike.Yramategui@intusurg.com
Date Summary Prepared:	March 12, 2019
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 SP1098, *EndoWrist SP* Instruments, and Accessories (K173906) *Intuitive Surgical*® *da Vinci Si*® Surgical System, Model IS3000 (K090993)

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 surgical 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 and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

EndoWrist SP® Instruments

Intuitive Surgical® EndoWrist SP® Instruments are controlled by the *da Vinci SP®* Surgical System, Model SP1098, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. The system is indicated for urologic surgical procedures that are appropriate for a single port approach and transoral otolaryngology surgical procedures in the oropharynx restricted to benign tumors and malignant tumors classified as T1 and T2. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Comparison of Technological Characteristics with the Predicate Device

The *da Vinci SP* Surgical System, Model SP1098 and *EndoWrist SP* Instruments and Accessories are unchanged from the predicate device, as cleared under K173906, in terms of intended use, design, performance, and technological characteristics. The only difference is that the labeling has been changed to include use in transoral otolaryngology procedures. Performance testing was conducted to evaluate the performance of the SP1098 for conducting all surgical tasks and representative procedures covered by the proposed Indications for Use. Additionally, the testing compared the safety and ability of the SP1098 and the *da Vinci Si* Surgical System, Model IS3000 to facilitate performance of surgical tasks, as well as facilitate completion of each representative surgical procedure, and to demonstrate functional equivalence between the SP1098 and the IS3000 (additional predicate device) for use in transoral otolaryngology procedures as cleared under K090993.

Table 1: Comparison of Subject and Predicate Devices

Attribute	**Subject Device** SP1098 *da Vinci SP* Surgical System, Instruments, and Accessories	**Primary Predicate Device:** SP1098 **(**K173906) **Additional Predicate Device**: IS3000 (K090993)
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	Primary Predicate Device: **SAME** Additional Predicate Device**:** **SAME** types of system carts as subject device. **SIMILAR** robotic arms, instruments and accessories. The primary difference is that the IS3000 *da Vinci Si* Surgical System utilizes four robotic arms and four ports to accommodate three surgical instruments and a camera. In contrast, the subject device (SP1098 *da Vinci SP* Surgical System) uses a single robotic arm to deliver three surgical instruments and a camera through a single port.
Common Name	Endoscopic instrument control system, endoscopic instruments and accessories	**SAME** as subject device

Table 1 (continued): Comparison of Subject and Predicate Devices

Attribute	**Subject Device** SP1098 *da Vinci SP* Surgical System, Instruments, and Accessories	**Primary Predicate Device:** SP1098 **(**K173906) **Additional Predicate Device**: IS3000 (K090993)
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 included bench, animal and cadaver testing, and a confirmatory clinical study to demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.

Bench Performance Testing

The addition of transoral otolaryngology surgical procedures to the SP1098 indications does not change any of the safety or performance requirements that were previously verified and/or validated for the SP1098 (K173906) regarding cleaning, sterilization, packaging, shelf life, biocompatibility, software, electrosurgical performance, electromagnetic compatibility, electrical safety, mechanical and electrical performance, reliability, or human factors. However, cleaning validation with a soil representative of TORS was performed (see table below) because it had not yet been completed for all the instruments and accessories at the time of the SP1098 clearance (K173906).

Table 2: Summary of Bench Performance Testing

Item	Testing
Camera Instrument	Cleaning Validation
Surgical Instruments	Cleaning Validation
Accessories	Cleaning Validation

FDA guidance documents used in bench performance testing: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff, issued March 17, 2015.

Cadaver and Animal Performance Testing

Comparative animal and cadaver testing was conducted to demonstrate the equivalence of the SP1098 System to the IS3000 System for performing transoral otolaryngology surgical (TORS) procedures. Cadavers were used to demonstrate device performance for anatomical access and reach. Live animals were used to assess safety and performance in cases where a live tissue model was appropriate. These models replicate factors experienced during normal clinical use, including working with perfused organs, normal tissue manipulation, and ensuring that appropriate hemostasis is achieved and maintained.

Three (3) independent practicing surgeons participated in a pre-clinical study using the SP1098 system to perform a set of transoral otolaryngology surgical procedures using both the SP1098 and the IS3000. Each surgeon performed four (4) procedures in

cadavers and two (2) procedures in a live porcine model with each system, for a total of eighteen (18) procedures performed with each system. Surgical success criteria for each procedure are listed below. In addition, surgeons completed questionnaires that evaluated their ability to perform surgical tasks with the two systems.

Table 3: Surgical Success Criteria in Animal and Cadaver Testing

Procedure	Subject	Surgical Success Criteria
Tongue base resection	Cadaver	• Resection volume is surgically acceptable • Resection boundaries achieved • Critical anatomy identified (e.g., lingual artery, lingual nerve, hypoglossal nerve) • No trauma to epiglottis
Lateral oropharyngectomy (aka, radical tonsillectomy)	Cadaver	• Resection volume is surgically acceptable • Resection boundaries achieved • Critical anatomy identified (e.g., medial pterygoid muscle, glossopharyngeal nerve)
Tongue base resection	Porcine	• Resection volume is surgically acceptable • Resection boundaries achieved • Critical anatomy identified (e.g., lingual artery, lingual nerve, hypoglossal nerve) • No trauma to epiglottis • Hemostasis maintained
Lateral oropharyngectomy (aka, radical tonsillectomy)	Porcine	• Resection volume is surgically acceptable • Resection boundaries achieved • Critical anatomy identified (e.g., medial pterygoid muscle, glossopharyngeal nerve) • Hemostasis maintained

Clinical Study

A prospective, multicenter, single-arm clinical study (NCT03049280) was conducted under an investigational device exemption (IDE #G160251) to confirm the safety and performance of the SP1098 *da Vinci SP* Surgical System, Instruments and Accessories in transoral robotic surgery (TORS) for malignant oropharyngeal tumors classified as T1 and T2. A total of 33 subjects were enrolled at three institutions in the United States.

Sixty four percent (64%) of subjects had one or more comorbid conditions which included hypertension, diabetes, chronic obstructive pulmonary disease (COPD), connective tissue, liver, renal or peptic ulcer disease. Thirty one (31) (93.9%) subjects underwent neck dissection, and they were either staged prior to TORS [sixteen (16)

(48.5%) subjects] or performed concomitantly with TORS [fifteen (15) (45.4%) subjects].

Safety was determined by incidence rate of device-related serious adverse events. Performance was determined by conversion rate from *da Vinci SP* to an open approach required to complete the indicated procedure. Results show that the device-related serious adverse event rate was 0%, and the conversion rate was 0%. Additional clinical study parameters were collected to demonstrate substantial equivalence to the predicate. Tables 4 and 5 below summarize the study data.

Table 4: TORS Clinical Study Summary (*da Vinci SP*)

Clinical Study Parameters	Study Data
Number of Patients, n	33
Operative time (min), mean ± SD	49.6 ± 33.1
Estimated blood loss (mL), mean ± SD	12.2 ± 18.7
Transfusion rate, %	0
Conversion to open rate, %	0
Device-related complication rate, %	0
Intraoperative complications, n	0
Length of hospital stay (days), mean ± SD	4.2 ±1.9
Rates of positive surgical margins, n (%)	1 (3.0)
Readmission rate, n (%)	3 (9.1)
Reoperation rate, n (%)	2 (6.1)
Mortality rate, %	0
Postoperative complications rates (non-device related), n (%)	8 (24.2)

Table 5: Postoperative Complications (8 study subjects)

Type	Number
Non-serious CTCAE I-II	
• Difficulty swallowing with increased secretions	1
• Fall	1
• Neck seroma	1
• Nasal regurgitation	1
• Difficulty opening mouth or trismus	1
Serious CTCAE III – IV	
• Hypoxemia leading to sequelae of altered mental status and hospital acquired pneumonia	1
• Hospital-acquired pneumonia	1
• Hemorrhage	1
• Clostridium difficile enterocolitis	1
• Left middle cerebral artery stroke leading to sequela of hemorrhage post TPA-administration	1

No intraoperative complications were observed and the safety endpoint was met. The bench, animal, cadaver and confirmatory clinical study demonstrate that SP1098 *da Vinci SP* Surgical System is as safe and effective as the predicate device.

Specific parameters of the clinical study were also compared to recently published clinical data between 2013 and 2018 on the *da Vinci Si* Surgical System for transoral otolaryngology surgery (TORS). In order to obtain the latest real world data on the predicate device, a systematic literature search of peer-reviewed publications was conducted using specific search criteria and filters.

Data from thirteen (13) publications reporting on transoral robotic surgery for cancer in the oropharynx with *da Vinci Si* Surgical System met these criteria and were included in the comparison. A detailed summary of this comparison of the *da Vinci SP* Surgical System data to the published clinical literature data on the *da Vinci Si* Surgical System is provided in Table 6 below for nine (9) parameters. Each parameter from the literature is shown based on its sample size, weighted average, weighted standard deviation and 95% confidence interval. The weighting has been performed according to the sample size of the study cohort using the weighted version of *proc univariate* within SAS version 9.4 for the calculations. The abstracted data is summarized in Table 7 at the end of this 510(k) Summary, and a bibliography of the literature is provided in Table 8.

Table 6: *da Vinci SP* versus *da Vinci Si* Literature Comparison

Clinical Parameter	Sources of Data	
	G160251/K182371	*da Vinci Si* - Literature[1-13]
Sample Size	N=33	N=9315
Operative Time (min), mean ± SD 95% CI	49.6 ± 33.1 [0, 114.5]	N=115 [4,7,8] 148.5 (± 71.0) [9.3, 287.7]
Estimated Blood Loss (mL), mean ± SD 95% CI	12.2 ± 18.7 [0, 48.9]	N=20 [8] 100 [a] [31.4, 168.6]
Transfusion rate, (%) 95% CI	0% [0, 10.4]*	N=1806 [3,10] 2.1% (±5.1) [0, 12.1]
Length of Hospital Stay (days), mean ± SD 95% CI	4.2 ±1.9 [0.5, 7.9]	N=2798 [2-4,7,8,10] 4.6 (±1.3) [b] [2.1, 7.2]
Conversion Rate from TORS (%) 95% CI	0% [0, 10.4]*	N=896 [2] 2.1% [1.3, 3.2]**
Mortality Rate (perioperative) (%) 95% CI	0% [0, 10.4]*	N=5307 [1,3,7,9-11,13] 0.52% (±0.62) [0, 1.7]
Readmission Rate (%) 95% CI	9.1% [3.1, 23.6]*	N=5265 [2,4,5,6,10,13] 8.8% (±3.1) [2.7, 14.9]
Reoperation Rate (%) 95% CI	6.1% [1.7, 19.7]*	N=1417 [5,10,12] 3.9% (±1.6) [0.8, 7.0]
Postoperative Complications (%) 95% CI	24.2% [12.8, 41.0]*	N=520 [4,5,7] 55.7% (±18.6) [c] [19.2, 92.2]

*Wilson (Score) 95% confidence interval, **Agresti Coull 95% confidence interval

Weighted averages, weighted standard deviations and 95% confidence intervals are provided for 7 of the 9 parameters from the literature; estimated blood loss and conversion rate are as reported in one publication.

Studies by Clayburgh D et al. (ref #4), and Chung TK et al. (ref #3), include multiple independent robotic cohorts used in the weighted average calculations for either discrete or continuous parameters.

[a]Median estimated blood loss is used in place of mean, and standard deviation was estimated using the range/4 reported by More et al.

[b]Median length of hospital stay is used in place of mean, standard deviation was estimated using the range/4 for both cohorts reported in Clayburgh D. et al. In the paper by Parhar HS. et al. (ref #10) mean length of hospital stay for 2 cohorts (readmissions and non- readmissions) is used in the overall calculation. Richmon J. et al. (ref#11) only reports a difference in length of hospital stay between robotic and non-robotic cohorts and is therefore not used in the overall calculation.

[c]Weighted mean postoperative complication rate includes the paper by Lee SY. et al. (ref #7) which reports only TORS related complications.

Comparison of results from the *da Vinci SP* Surgical System to the published literature on the *da Vinci Si* Surgical System demonstrate that the point estimate of all 9 parameters from the *da Vinci SP* study fall within or below the 95% confidence intervals calculated from the published clinical literature on *da Vinci Si*.

- Operative time
- Transfusion rate
- Length of hospital stay
- Readmission rate
- Post-operative complications rate
- Estimated blood loss
- Conversion rate from TORS to open
- Mortality rate
- Reoperation rate

This comparison was used to demonstrate that the *da Vinci SP* Surgical System is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

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 devices. This SE determination is based on performance testing that included: bench, cadaver, and animal testing with simulated and representative transoral otolaryngology surgical procedures, and a confirmatory clinical study. The bench performance testing verified that the instruments and accessories could be cleaned when exposed to soiling expected in transoral otolaryngology surgical procedures. 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 transoral otolaryngology surgical procedures in live animals validated that the system can be used to successfully complete the representative transoral otolaryngology surgical procedures encompassed by the indications for use statement. The confirmatory clinical study showed that the results experienced in the cadaver and animal study reflect the results experienced in a human clinical setting, and that there are no different questions of safety or effectiveness compared to the predicate device. A complete list of postoperative complications experienced in the clinical study is provided in Table 5, and Table 6 provides a comparison of clinical parameters from the study on *da Vinci SP* (subject device) and published clinical literature on *da Vinci Si* (predicate device), and supports substantial equivalence for performing transoral otolaryngology surgical procedures.

Table 7: Abstracted Data from Clinical Literature on *da Vinci Si*

Author	Cohort	Study Size	Operation Time (min)	Blood Transfusion (%)	EBL (mL)	Length of Stay (days)	Conversions	Postop Complication Rate (30-days) (%)	Mortality Rate (in-hospital or 30 days) (%)	Readmission Rate (30-days) (%)	Reoperation Rate (30-days) (%)
1. Baliga S (2018)	Robotic	2680	NR	NR	NR	NR	NR	NR	0.4%	NR	NR
2. Chen MM (2014)	Robotic	877	NR	NR	NR	4.7 (SE 0.2)	19/896 (2.1%)	NR	NR	4.40%	NR
3. Chung TK (2015)	Robotic partial pharyngectomy - mild/moderate	523	NR	0%	NR	3.7 ± 2.2	NR	NR	0%	NR	NR
	Robotic partial pharyngectomy - major/extreme	118		21.20%	NR	7.6 ± 7.0			4.20%		
	Robotic partial glossectomy for BOT Ca (mild/moderate)	147		0%	NR	3.54 ± 2.61			0%		
	Robotic partial glossectomy for anterior tongue ca (mild/moderate)	68		0%	NR	4.8 ± 3.1			0%		
4. Clayburgh D (2017)	Robotic placebo	33	202 ± 51	NR	NR	median 5 (range 2-11)	NR	7/33 (21.2%)	NR	0	NR
	Robotic steroid	35	211 ± 61		NR	median 4 (range 2-6)		10/35 (28.6%)		2/35 (5.7%)	
5. Frenkel CH (2017)	Robotic	425	NR	NR	NR	NR	NR	273/425 (64.2%)	NR	56/425 (13.2%)	26/425 (6.1%)
6. Goel AN (2018)	Robotic	2576	NR	NR	NR	NR	NR	NR	NR	236/2576 (9.2%)	NR
7. Lee SY (2013)	Robotic	27	48.3 ± 7.5	NR	NR	14.6 ± 4	NR	TORS related comps: 0%	0%	NR	NR
8. More YI (2013)	Robotic	20	86 ± 36	NR	100 (60-200)	2 (1-4)	NR	NR		NR	NR
9. Motz K (2017)	Robotic	304	NR	NR	NR	NR	NR	NR	1.00%	NR	NR
10. Parhar HS (2018)	Robotic	955	NR	13/950 (1.4%)	NR	Readmit: 5.7 ± 6.8 not readmit: 4.3 ± 4.1	NR	NR	5/955 (0.5%)	117/950 (12.3%)	27/950 (2.8%)
11. Richmon J (2014)	Robotic	116	NR	NR	NR	-1.5	NR	NR	0%	NR	NR
12. Smith RV (2015)	Robotic	42	NR	NR	NR	NR	NR	NR	NR	NR	3/42 (7.1%)
13. Zevallos JP (2016)	Robotic	369	NR	NR	NR	NR	NR	NR	4/369 (1.1%)	14/369 (3.8%)	NR

NR: Not reported

Table 8: Bibliography of Clinical Literature on *da Vinci Si*

#	Publication
1	Baliga S, Kabarriti R, Jiang J, et al. Utilization of Transoral Robotic Surgery (TORS) in patients with Oropharyngeal Squamous Cell Carcinoma and its impact on survival and use of chemotherapy. Oral Oncology. 2018;86:75-80.
2	Chen MM, Roman SA, Kraus DH, Sosa JA, Judson BL. Transoral Robotic Surgery: A Population-Level Analysis. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2014.
3	Chung TK, Rosenthal EL, Magnuson JS, Carroll WR. Transoral robotic surgery for oropharyngeal and tongue cancer in the United States. The Laryngoscope. 2014.
4	Clayburgh D, Stott W, Bolognone R, et al. A randomized controlled trial of corticosteroids for pain after transoral robotic surgery. The Laryngoscope. 2017.
5	Frenkel CH, Yang J, Zhang M, Altieri MS, Telem DA, Samara GJ. Compared Outcomes of Concurrent versus Staged Transoral Robotic Surgery with Neck Dissection. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2017:194599817706499.
6	Goel AN, Badran KW, Mendelsohn AH, et al. Readmission after surgery for oropharyngeal cancer: An analysis of rates, causes, and risk factors. The Laryngoscope. 2018.
7	Lee SY, Park YM, Byeon HK, Choi EC, Kim SH. Comparison of oncologic and functional outcomes after transoral robotic lateral oropharyngectomy versus conventional surgery for T1 to T3 tonsillar cancer. Head & neck. 2013;36(8):1138-1145.
8	More YI, Tsue TT, Girod DA, et al. Functional swallowing outcomes following transoral robotic surgery vs primary chemoradiotherapy in patients with advanced-stage oropharynx and supraglottis cancers: Comment. *Dysphagia.* 2013;28(4):593-594.
9	Motz K, Chang HY, Quon H, Richmon J, Eisele DW, Gourin CG. Association of Transoral Robotic Surgery With Short-term and Long-term Outcomes and Costs of Care in Oropharyngeal Cancer Surgery. *JAMA otolaryngology-- head & neck surgery.* 2017. Motz K, Chang H-Y, Quon H, Richmon J, Eisele DW, Gourin CG. Association of transoral robotic surgery with short-term and long-term outcomes and costs of care in oropharyngeal cancer surgery. Supplementary Online Content. *JAMA Otolaryngol Head Neck Surg*. Published online March 30, 2017.
10	Parhar HS, Gausden E, Patel J, et al. Analysis of readmissions after transoral robotic surgery for oropharyngeal squamous cell carcinoma. *Head Neck.* 2018.
11	Richmon J, Quon H, Gourin CG. The effect of transoral robotic surgery on short-term outcomes and cost of care after oropharyngeal cancer surgery. *The Laryngoscope.* 2013.
12	Smith RV, Schiff BA, Garg M, Haigentz M. The impact of transoral robotic surgery on the overall treatment of oropharyngeal cancer patients. *The Laryngoscope.* 2015;125 Suppl 10:S1-s15.
13	Zevallos JP, Mitra N, Swisher-McClure S. Patterns of care and perioperative outcomes in transoral endoscopic surgery for oropharyngeal squamous cell carcinoma. *Head Neck.* 2014.