Intuitive Surgical, Inc.
Kunal Gunjal
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

November 18, 2024

Re: K241814
Trade/Device Name: da Vinci SP Instruments (SP1098)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: June 20, 2024
Received: June 24, 2024

Dear Kunal Gunjal:

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 (the 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 available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

The OHT4: Office of Surgical and Infection Control Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the 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 and general thoracoscopic surgical 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR

830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

BLETA VUNIQI -S

Digitally signed by BLETA VUNIQI -S
Date: 2024.11.18 17:41:04 -05'00'

for Binita Ashar, M.D., M.B.A., F.A.C.S. M.A.M.S.E.
Director
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241814

Device Name

da Vinci SP Instruments (SP1098)

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

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Kunal Gunjal
Senior Regulatory Affairs Specialist
Email: Kunal.Gunjal@intusurg.com

Date Summary Prepared: November 18, 2024

Trade Name: *da Vinci SP Instruments* as listed in ***Table 1****:*

Table 1: da Vinci SP Instruments

SP Instruments Category	***da Vinci SP* Instrument Name**	***da Vinci SP* Instrument Model Numbers**
SP Force Bipolar Instruments	SP Force Bipolar	430150
	SP Force Bipolar, Extended Range	431150
SP *"Extended Range"* Instruments	SP Maryland Bipolar Forceps, Extended Range	431152
	SP Cadiere Forceps, Extended Range	431300
	SP Needle Driver Extended Range	431200
	SP Monopolar Curved Scissors Extended Range	431100
	SP Round Tooth Retractor Extended Range	431301
SP *"Enhanced Wrist"* Instruments	SP Maryland Bipolar Forceps	430152
	SP Cadiere Forceps	430300
	SP Needle Driver	430200
	SP Monopolar Curved Scissors	430100
	SP Monopolar Cautery Instrument	430101
	SP Fenestrated Bipolar Forceps	430151
SP Medium Large Clip Applier		430250

Common Name: Endoscope 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/Reference Devices: Refer to Predicate and Reference Devices listed in **Table 2**.

Table 2 : Predicate/Reference Devices

Predicate/Reference Devices	***da Vinci SP* Instruments**	**Model #(s)**	**510(k) #**
Predicate Device	SP Maryland Bipolar Forceps	430010	K240502
	SP Cadiere Forceps	430009	
	SP Needle Driver	430006	
	SP Monopolar Curved Scissors	430004	
	SP Monopolar Cautery Instrument	430007	
	SP Fenestrated Bipolar Forceps	430011	
	SP Round Tooth Retractor	430002	
	SP Medium-Large Clip Applier	430005	
Reference Device	*EndoWrist*® Mercury Bipolar Grasper (also referred to as *da Vinci Xi* Force Bipolar)	470405	K180351

Device Description

The *da Vinci SP* Surgical System, Model SP1098 is a software-controlled, electro-mechanical system designed for surgeons to perform 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, *da Vinci SP* Instruments, and Accessories. 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 *da Vinci 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, SP Access Port and 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 *da Vinci 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 *da Vinci 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.

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 and general thoracoscopic 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 and general thoracoscopic 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/Reference Device(s)

The modifications to the SP1098 System include introduction of new SP Instruments:

SP Force Bipolar Instruments

The Force Bipolar is intended to be used with the *da Vinci SP* system for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels. The Force Bipolar is also intended for grasping and manipulating compatible bulldog clamps. The Force Bipolar is a 6 mm, multi-use instrument with bipolar energy capability. This instrument allows the user to temporarily apply a Strong Grip Mode, depending on surgical needs. The default SP Force Bipolar grip is the same as the SP Fenestrated Bipolar Forceps (*PN 430011, cleared in the predicate device submission, K240502*) and operates in this grip until the user applies Strong Grip Mode. While operating in Strong Grip Mode, the instrument has grip characteristics that are 50% greater than the Force Bipolar default mode. The change in the grip mode setting from DEFAULT to STRONG and vice versa is enabled by a software algorithm, *"GripSelect"*. The *Grip Selection* feature on the subject device essentially combines the capabilities of two instruments into a single instrument. The *"Grip Selection feature"* on the subject devices (SP Force Bipolar Instruments) is IDENTICAL to the reference device (*EndoWrist*® Mercury *Bipolar Grasper, also referred to as da Vinci Xi Force Bipolar cleared via K180351*). The SP Force Bipolar Instrument is available in two versions: *SP Force Bipolar, Standard Range (PN 430150)* and *SP Force Bipolar, Extended Range (PN 431150)*. The Standard and Extended Range instruments have the same features, except the Extended Range instruments have a longer forearm allowing for extended lateral range of motion (as shown in ***Figure 1***).

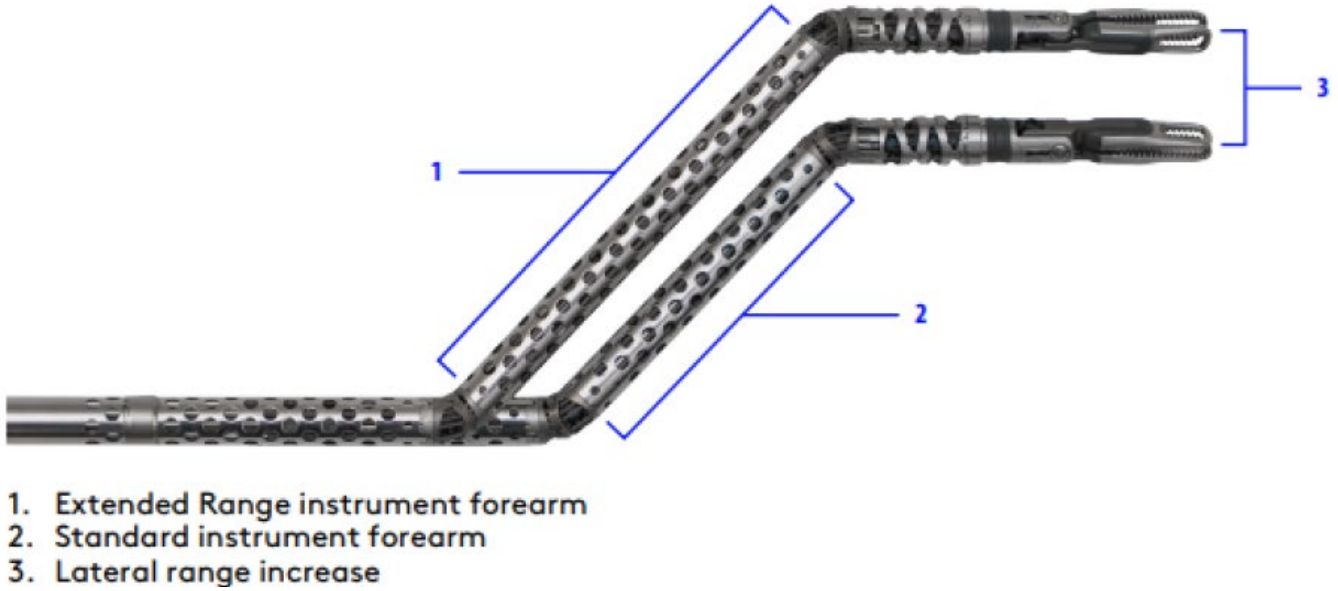

Figure 1: Standard versus Extended Range SP Force Bipolar Instrument Comparison

SP Instruments with Long Joggle (also referred to as *"Extended Range Instruments"*)

Introduction of long joggle versions of SP instruments (*also referred to as "Extended Range" Instruments*), as compared to the standard joggle instruments (*previously cleared in the predicate device submission, K240502*), as listed in ***Table 3***, intended to be used with *da Vinci SP* Surgical System. The Standard and Extended Range instruments have the same features and the same overall instrument length, except the Extended Range instruments have a longer forearm allowing for extended lateral range of motion (as shown in ***Figure 2 and 3)***.

Additionally, the wrist range of motion is increased from 72 degrees (predicate device instrument's physical limit) to 86 degrees (subject device instrument's software limit), as shown in ***Figure 4***.

Table 3 : Subject Devices and Predicate Devices, da Vinci SP Instruments

Subject Device SP Instruments (K241814)		**Predicate Device SP Instruments (K240502)**	
***da Vinci SP Long Joggle Instruments (also referred to as "Extended Range"* Instruments)**	***da Vinci SP* Instrument Model Numbers**	***da Vinci SP Standard Joggle Instruments***	***da Vinci SP* Instrument Model Numbers**
SP Maryland Bipolar Forceps, Extended Range	431152	SP Maryland Bipolar Forceps	430010
SP Cadiere Forceps, Extended Range	431300	SP Cadiere Forceps	430009
SP Needle Driver, Extended Range	431200	SP Needle Driver	430006
SP Monopolar Curved Scissors, Extended Range	431100	SP Monopolar Curved Scissors	430004
SP Round Tooth Retractor, Extended Range	431301	SP Round Tooth Retractor	430002

Note: The only change to the SP Round Tooth Retractor (PN 431301) as compared to its predicate device (SP Round Tooth Retractor, PN 430002) are Wrist ROM changes. Both the subject and predicate SP Round Tooth Retractor instruments have a long joggle.

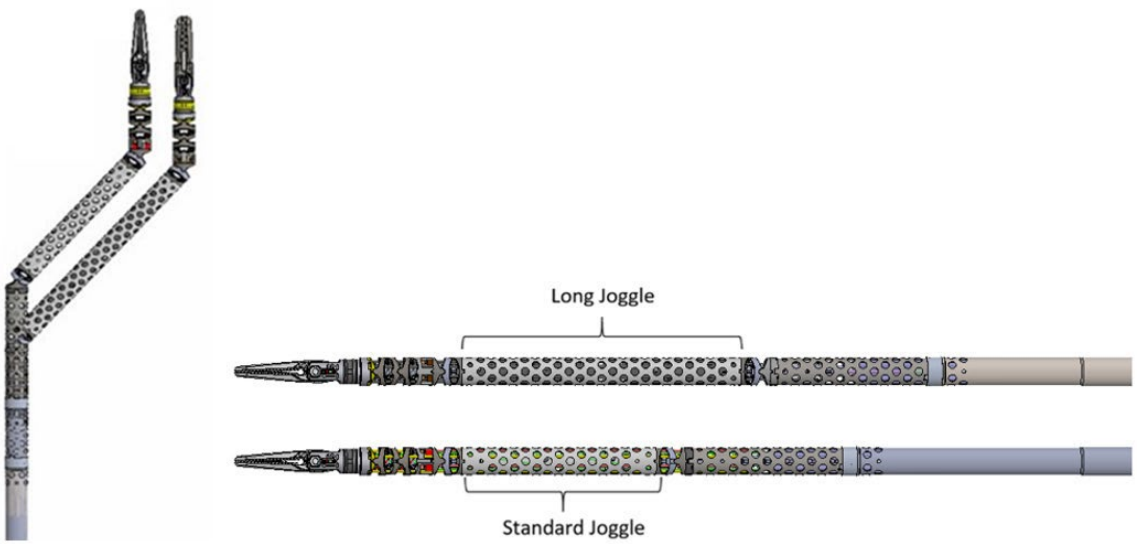

Figure 2: Subject Devices and Predicate Device, da Vinci SP Instruments (Long Joggle and Standard Joggle)

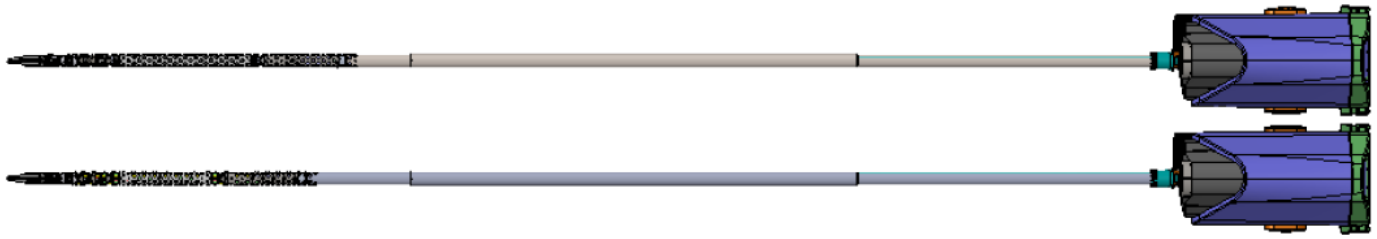

Figure 3: Standard Joggle versus Long Joggle Instrument Comparison – Same Overall Instrument Length

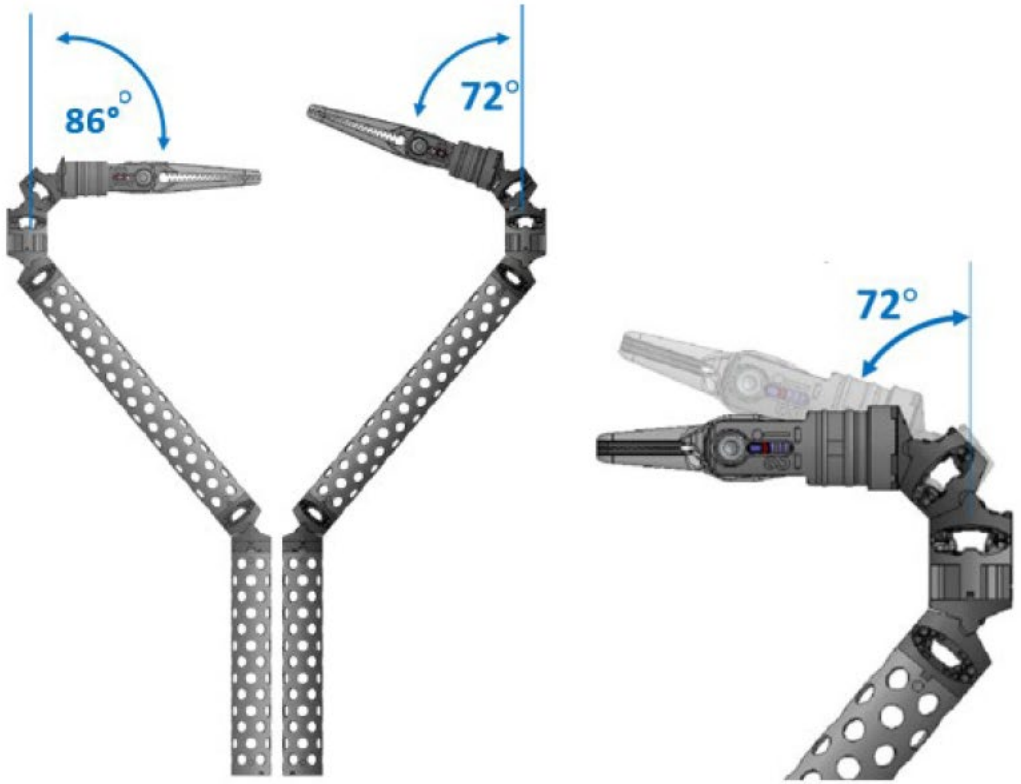

Figure 4: Right- Standard Joggle Instruments (Predicate devices, cleared via K240502) VS Left- Long Joggle "Extended Range" Instruments (subject devices)

SP Instruments with increased Wrist Range of Motion (ROM), also referred to as *"Enhanced Wrist"* Instruments

Introduction of new SP Instruments with Standard Joggle with increased Wrist Range of Motion (ROM) (*also referred to as "Enhanced Wrist" Instruments*), as compared to the standard joggle instruments (*previously cleared in the predicate device submission, K240502*), as listed in ***Table 4***, intended to be used with *da Vinci SP* Surgical System.

The *Enhanced Wrist* SP Instruments (subject devices) and the predicate device instruments have the same features and the same overall instrument length, except the wrist range of motion is increased from 72 degrees (predicate device instrument's physical limit) to 86 degrees (subject device instrument's software limit), as shown in ***Figure 5***.

Table 4 : Subject Devices and Predicate Devices, da Vinci SP Instruments

Subject Device SP Instruments (K241814)		**Predicate Device SP Instruments (K240502)**	
da Vinci SP Standard Joggle Instruments with increased Wrist Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)	***da Vinci SP* Instrument Model Numbers**	***da Vinci SP Standard Joggle Instruments***	***da Vinci SP* Instrument Model Numbers**
SP Maryland Bipolar Forceps	430152	SP Maryland Bipolar Forceps	430010
SP Cadiere Forceps	430300	SP Cadiere Forceps	430009
SP Needle Driver	430200	SP Needle Driver	430006
SP Monopolar Curved Scissors	430100	SP Monopolar Curved Scissors	430004
SP Monopolar Cautery Instrument	430101	SP Monopolar Cautery Instrument	430007
SP Fenestrated Bipolar Forceps	430151	SP Fenestrated Bipolar Forceps	430011

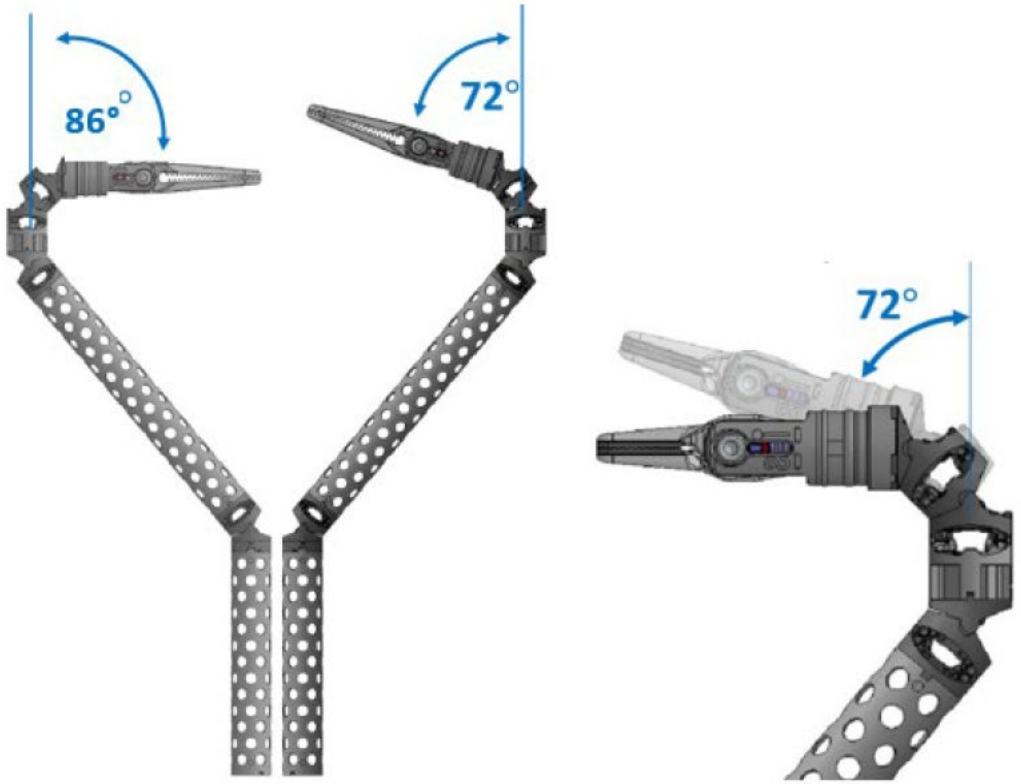

Figure 5: Right- Standard Joggle Instruments (Predicate devices, cleared via K240502) VS Left- Standard Joggle "Enhanced Wrist" Instruments (subject devices)

SP Medium-Large Clip Applier

There are no design changes to the SP Medium-Large Clip Applier, relative to the predicate device**.** The labeled and programmed Model (#) was updated as noted in **Table 5**.

Table 5 : Subject Device and Predicate Device, da Vinci SP Instruments

Subject Device SP Instrument (K241814)		**Predicate Device SP Instrument (K240502)**	
da Vinci SP Instrument	***da Vinci SP* Instrument Model Number**	***da Vinci SP Instrument***	***da Vinci SP* Instrument Model Number**
SP Medium-Large Clip Applier	430250	SP Medium-Large Clip Applier	430005

Comparison of Predicate and Subject Devices (*da Vinci SP* Force Bipolar Instruments)

Table 6 includes a comparison of the subject devices (*da Vinci SP* Force Bipolar Instruments) and the *Predicate Device, SP Fenestrated Bipolar Forceps cleared via K240502* and *Reference Device, EndoWrist®* Mercury *Bipolar Grasper, also referred to as da Vinci Xi Force Bipolar cleared via K180351*. Differences in the Characteristics as noted in ***Table 6*** are marked by ***GREYING OUT*** the specific rows. Additionally, any differences in the specific characteristics within these rows are ***BOLDED***.

The SP Force Bipolar instruments allow the user to temporarily apply a Strong Grip Mode, depending on surgical needs. The default SP Force Bipolar grip is the same as the *SP Fenestrated Bipolar Forceps (PN 430011, cleared in the predicate device submission, K240502)* and operates in this grip until the user applies Strong Grip Mode. While operating in Strong Grip Mode, the instrument has grip characteristics that are 50% greater than the Force Bipolar default mode. The change in the grip mode setting from DEFAULT to STRONG and vice versa is enabled by a software algorithm, *"GripSelect"*. The *Grip Selection feature* on the subject device essentially combines the capabilities of two instruments into a single instrument. The *"Grip Selection feature"* on the subject devices (SP Force Bipolar Instruments) is IDENTICAL to the reference device (*EndoWrist® Mercury Bipolar Grasper, also referred to as da Vinci Xi Force Bipolar cleared via K180351*).

There are no significant user facing changes on the SP Force Bipolar Instruments, as compared to the predicate device (*SP Fenestrated Bipolar Forceps, cleared in K240502)* and the reference device (*da Vinci Xi Force Bipolar/Mercury Bipolar Grasper, cleared in K180351*). The user facing changes to the SP Force Bipolar Instruments (subject devices), regarding changing the grip strength from *"Default" mode to "Strong" mode*, and vice versa, from the Surgeon Console is identical to the reference device, the *da Vinci Xi* Force Bipolar Instrument (*cleared via K180351*). Additionally, both the Xi and SP Surgical System use the same Surgeon Console sub-system.

No additional human factors testing was warranted for the SP Force Bipolar Instruments and the human factors validation testing which was performed on the predicate and reference devices (K240502 and K180351), was leveraged for the SP Force Bipolar Instruments.

Performance testing (bench, animal, and cadaver tests) on the subject devices (SP Force Bipolar Instruments), as summarized in ***Table 10***, demonstrates that the subject devices are substantially equivalent to the predicate device (K240502) and does not raise different questions of safety and effectiveness than the predicate device.

Table 6: Comparison of Predicate and Subject Devices (da Vinci SP Force Bipolar Instruments)

Characteristic	**Subject Device** *da Vinci SP* Force Bipolar Instruments (K241814)	**Predicate Device** *da Vinci SP* Fenestrated Bipolar Forceps (K240502)	**Reference Device** *EndoWrist*® Mercury Bipolar Grasper (K180351)
General Information			
Manufacturer	Intuitive Surgical, Inc.	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device
Trade Name	*da Vinci SP* Force Bipolar Instruments	*da Vinci SP* Fenestrated Bipolar Forceps	*EndoWrist*® Mercury Bipolar Grasper
Model #	*da Vinci SP* Force Bipolar (PN 430150) *da Vinci SP* Force Bipolar, Extended Range (PN 431150)	*da Vinci SP* Fenestrated Bipolar Forceps (PN 430011)	*EndoWrist*® Mercury Bipolar Grasper (PN 470405)
Common Name	Endoscope and accessories	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device
Regulation Number	21 CFR 876.1500	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *da Vinci SP* Force Bipolar Instruments (K241814)	**Predicate Device** *da Vinci SP* Fenestrated Bipolar Forceps (K240502)	**Reference Device** *EndoWrist*® Mercury Bipolar Grasper (K180351)
Product Code	NAY, GCJ	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device
Device Classification	Class II	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device
Classification Advisory Committee	General and Plastic Surgery	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device
System Compatibility	Compatible with the SP1098 system	Compatible with the SP1098 system	Compatible with the *da Vinci Xi* System
Intended Use	The ***Force Bipolar*** is intended to be used with the da Vinci SP System for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels. The ***Force Bipolar*** is also intended for grasping and manipulating compatible bulldog clamps.	The ***Fenestrated Bipolar Forceps*** is intended to be used with the da Vinci SP System for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels. The ***SP Fenestrated Bipolar Forceps*** is also intended for grasping and manipulating compatible bulldog clamps.	The ***EndoWrist*** **Mercury Bipolar Grasper** is intended to be used with compatible systems for endoscopic manipulation of tissue, including dissection, grasping, retraction, and bipolar coagulation of tissue.

Indications for Use	<u>da Vinci SP Surgical System, Model SP1098:</u> 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 and general thoracoscopic 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. <u>EndoWrist SP Instruments:</u> 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,	**IDENTICAL** to the subject device	<u>da Vinci Xi (IS4000) System</u> The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi 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.

Characteristic	**Subject Device** *da Vinci SP* Force Bipolar Instruments (K241814)	**Predicate Device** *da Vinci SP* Fenestrated Bipolar Forceps (K240502)	**Reference Device** *EndoWrist*® Mercury Bipolar Grasper (K180351)
	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 and general thoracoscopic 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.		

Characteristic	**Subject Device** *da Vinci SP* Force Bipolar Instruments (K241814)	**Predicate Device** *da Vinci SP* Fenestrated Bipolar Forceps (K240502)	**Reference Device** *EndoWrist*® Mercury Bipolar Grasper (K180351)
Prescription use	Prescription/Physician use only	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device
Number of Lives and Reprocessing Cycles	**Number of Lives: 20** **Number of Reprocessing Cycles: 30**	**IDENTICAL** to the subject device	**Number of Lives: 10** **Number of Reprocessing Cycles: 15**
Where used (hospital, home, ambulance, etc)	Hospital	**IDENTICAL** to the subject device	**IDENTICAL** to the subject device

Comparison of Predicate and Subject Devices, *SP Instruments with Long Joggle (also referred to as "Extended Range" Instruments*)

Table 7 includes a comparison of the subject device(s) (SP Instruments with Long Joggle, also referred to as *"Extended Range"* Instruments) and the predicate device(s) (*SP Instruments cleared via K240502*). Differences in the Characteristics as noted in ***Table 7*** are marked by ***GREYING OUT*** the specific rows. Additionally, any differences in the specific characteristics within these rows are ***BOLDED***.

The technological characteristics such as principles of operation remain unchanged between the predicate device and the subject devices. The subject devices (*da Vinci SP Instruments with Long Joggle, also referred to as "Extended Range" Instruments*) include the following design changes as compared to the standard joggle SP Instruments (*predicate devices cleared via K240502*):

- Longer Joggle Length (as shown in ***Figure 2*** and ***Figure 3***)
- Wrist ROM updates (as shown in ***Figure 4***)
- Design Changes to support increased Wrist ROM on Long Joggle *"Extended Range"* SP Instruments

There are no significant user facing changes on the *Extended Range* Instruments (subject devices), as compared to the predicate SP Instruments (cleared in K240502). Hence no additional human factors testing was warranted for the SP *Extended Range* Instruments, and the human factors testing which was performed on the predicate devices (K240502), was leveraged for the subject devices.

Performance testing (bench, animal, and cadaver tests), as summarized in ***Table 10***, demonstrate that the subject device (SP *Extended Range* Instruments) is substantially equivalent to the predicate device (K240502) and does not raise different questions of safety and effectiveness than the predicate device.

Table 7: Comparison of Predicate and Subject Devices (SP Instruments with Long Joggle (also referred to as "Extended Range" Instruments)

<table>
<tr><th>Characteristic</th><th>Subject Device
SP Instruments with Long Joggle (also referred to as "Extended Range" Instruments
(K241814)</th><th>Predicate Device
da Vinci SP Instruments (K240502)</th></tr>
<tr><td colspan="3">General Information</td></tr>
<tr><td>Manufacturer</td><td>Intuitive Surgical, Inc.</td><td>IDENTICAL to the subject device</td></tr>
<tr><td>Trade Name</td><td>da Vinci SP Instruments</td><td>IDENTICAL to the subject device</td></tr>
<tr><td>Model #</td><td>
<table>
<tr><th>da Vinci SP Long Joggle Instruments (also referred to as "Extended Range" Instruments)</th><th>Model #</th></tr>
<tr><td>SP Maryland Bipolar Forceps, Extended Range</td><td>431152</td></tr>
<tr><td>SP Cadiere Forceps, Extended Range</td><td>431300</td></tr>
<tr><td>SP Needle Driver, Extended Range</td><td>431200</td></tr>
<tr><td>SP Monopolar Curved Scissors, Extended Range</td><td>431100</td></tr>
<tr><td>SP Round Tooth Retractor, Extended Range</td><td>431301</td></tr>
</table>
</td><td>
<table>
<tr><th>da Vinci SP Standard Joggle Instruments</th><th>Model #</th></tr>
<tr><td>SP Maryland Bipolar Forceps</td><td>430010</td></tr>
<tr><td>SP Cadiere Forceps</td><td>430009</td></tr>
<tr><td>SP Needle Driver</td><td>430006</td></tr>
<tr><td>SP Monopolar Curved Scissors</td><td>430004</td></tr>
<tr><td>SP Round Tooth Retractor</td><td>430002</td></tr>
</table>
</td></tr>
<tr><td>Common Name</td><td>Endoscope and accessories</td><td>IDENTICAL to the subject device</td></tr>
</table>

Characteristic	**Subject Device** *SP Instruments with Long Joggle (also referred to as "Extended Range" Instruments* (K241814)	**Predicate Device** *da Vinci SP* Instruments (K240502)
Regulation Number	21 CFR 876.1500	**IDENTICAL** to the subject device
Product Code	NAY, GCJ	**IDENTICAL** to the subject device
Device Classification	Class II	**IDENTICAL** to the subject device
Classification Advisory Committee	General and Plastic Surgery	**IDENTICAL** to the subject device
System Compatibility	Compatible with the SP1098 system	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *SP Instruments with Long Joggle (also referred to as "Extended Range" Instruments* (K241814)	**Predicate Device** *da Vinci SP* Instruments (K240502)
Intended Use	**Intended Use:** ○ ***SP Maryland Bipolar Forceps, Extended Range***: The Maryland Bipolar Forceps is intended to be used with the *da Vinci SP* System for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels. ○ ***SP Cadiere Forceps, Extended Range:*** The Cadiere Forceps is intended to be used with the *da Vinci SP* System for dissecting, grasping, manipulating, and retracting tissues. The SP Cadiere Forceps is also intended for grasping and manipulating compatible bulldog clamps. ○ ***SP Needle Driver, Extended Range:*** The Needle Driver is intended to be used with the *da Vinci SP* System to drive needles through tissue and handle and tie suture. ○ ***SP Monopolar Curved Scissors, Extended Range:*** The Monopolar Curved Scissors with MCS Tip is intended to be used with the *da Vinci SP* System for manipulating, cutting, and dissecting tissue, coagulating and transecting tissue using monopolar electrosurgical energy, and cutting suture. ○ ***SP Round Tooth Retractor, Extended Range***: The Round Tooth Retractor is intended to be used with the *da Vinci SP* System for retracting, grasping and manipulating tissues.	**IDENTICAL** to the subject device

Indications for Use	<u>da Vinci SP Surgical System, Model SP1098:</u> 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 and general thoracoscopic 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. <u>EndoWrist SP Instruments:</u> 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 and general thoracoscopic 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.	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *SP Instruments with Long Joggle (also referred to as "Extended Range" Instruments* (K241814)	**Predicate Device** *da Vinci SP* Instruments (K240502)
Prescription use	Prescription/Physician use only	**IDENTICAL** to the subject device
Where used (hospital, home, ambulance, etc)	Hospital	**IDENTICAL** to the subject device

<table>
<tr><th>Characteristic</th><th>Subject Device
SP Instruments with Long Joggle (also referred to as “Extended Range” Instruments
(K241814)</th><th>Predicate Device
da Vinci SP Instruments (K240502)</th></tr>
<tr><td>Number of Lives and Reprocessing Cycles</td><td>
<table>
<tr><th colspan="4">Subject Device SP Instruments</th></tr>
<tr><th>da Vinci SP Long Joggle Instruments (also referred to as “Extended Range” Instruments)</th><th>da Vinci SP Instrument Model Numbers</th><th>Number of Lives</th><th>Number of Reprocessing Cycles</th></tr>
<tr><td>SP Maryland Bipolar Forceps, Extended Range</td><td>431152</td><td>25</td><td>38</td></tr>
<tr><td>SP Cadiere Forceps, Extended Range</td><td>431300</td><td>25</td><td>38</td></tr>
<tr><td>SP Needle Driver, Extended Range</td><td>431200</td><td>25</td><td>38</td></tr>
<tr><td>SP Monopolar Curved Scissors, Extended Range</td><td>431100</td><td>25</td><td>38</td></tr>
<tr><td>SP Round Tooth Retractor, Extended Range</td><td>431301</td><td>25</td><td>38</td></tr>
</table>
</td><td>
<table>
<tr><th colspan="4">Predicate Device SP Instruments (K240502)</th></tr>
<tr><th>da Vinci SP Standard Joggle Instruments</th><th>da Vinci SP Instrument Model Numbers</th><th>Number of Lives</th><th>Number of Reprocessing Cycles</th></tr>
<tr><td>SP Maryland Bipolar Forceps</td><td>430010</td><td>20</td><td>30</td></tr>
<tr><td>SP Cadiere Forceps</td><td>430009</td><td>22</td><td>33</td></tr>
<tr><td>SP Needle Driver</td><td>430006</td><td>22</td><td>33</td></tr>
<tr><td>SP Monopolar Curved Scissors</td><td>430004</td><td>20</td><td>30</td></tr>
<tr><td>SP Round Tooth Retractor</td><td>430002</td><td>20</td><td>30</td></tr>
</table>
</td></tr>
<tr><td>Compatible System</td><td>SP1098 Surgical System</td><td>IDENTICAL to the subject device</td></tr>
<tr><td>Principle of Operation</td><td colspan="2">There are no changes to the Principle of Operation between the subject and predicate devices.</td></tr>
</table>

Comparison of Predicate and Subject Devices (*da Vinci SP Instruments with Standard Joggle with increased Wrist Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)*

Table 8 includes a comparison of the subject device(s) (*da Vinci SP* Instruments with Standard Joggle with increased Wrist Range of Motion (ROM), also referred to as *"Enhanced Wrist"* Instruments) and the predicate device(s) (*SP Instruments cleared via K240502*). Differences in the Characteristics as noted in ***Table 8*** are marked by ***GREYING OUT*** the specific rows. Additionally, any differences in the specific characteristics within these rows are ***BOLDED***.

The technological characteristics such as principles of operation remain unchanged between the predicate device and the subject devices. The subject devices (*da Vinci SP* Instruments with increased Wrist Range of Motion (ROM), also referred to as *"Enhanced Wrist"* Instruments), include the following design changes as compared to the standard joggle SP Instruments (predicate devices cleared in K240502):

- Wrist ROM updates (as shown in ***Figure 5***)
- Design Changes to support increased Wrist ROM

There are no significant user facing changes on the *Enhanced Wrist* Instruments (subject devices), as compared to the predicate SP Instruments (cleared in K240502). Hence no additional human factors testing was warranted for the SP *Enhanced Wrist* Instruments, and the human factors testing which was performed on the predicate devices (K240502), was leveraged for the subject devices.

Performance testing (bench, animal, and cadaver tests), as summarized in ***Table 10***, demonstrate that the subject device (SP *Enhanced Wrist* Instruments) is substantially equivalent to the predicate device (K240502) and does not raise different questions of safety and effectiveness than the predicate device.

Table 8: Comparison of Predicate and Subject Devices (da Vinci SP Instruments with Standard Joggle with increased Wrist Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)

<table>
<tr><th>Characteristic</th><th>Subject Device

da Vinci SP Instruments with increased WRIST Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)

(K241814)</th><th>Predicate Device

da Vinci SP Instruments (K240502)</th></tr>
<tr><td colspan="3">General Information</td></tr>
<tr><td>Manufacturer</td><td>Intuitive Surgical, Inc.</td><td>IDENTICAL to the subject device</td></tr>
<tr><td>Trade Name</td><td>da Vinci SP Instruments</td><td>IDENTICAL to the subject device</td></tr>
<tr><td>Model #</td><td>
<table>
<tr><th>da Vinci SP Instruments with Enhanced WRIST Range of Motion (ROM)</th><th>Model #</th></tr>
<tr><td>SP Maryland Bipolar Forceps</td><td>430152</td></tr>
<tr><td>SP Cadiere Forceps</td><td>430300</td></tr>
<tr><td>SP Needle Driver</td><td>430200</td></tr>
<tr><td>SP Monopolar Curved Scissors</td><td>430100</td></tr>
<tr><td>SP Monopolar Cautery Instrument</td><td>430101</td></tr>
<tr><td>SP Fenestrated Bipolar Forceps</td><td>430151</td></tr>
</table>
</td><td>
<table>
<tr><th>da Vinci SP Standard Joggle Instruments</th><th>Model #</th></tr>
<tr><td>SP Maryland Bipolar Forceps</td><td>430010</td></tr>
<tr><td>SP Cadiere Forceps</td><td>430009</td></tr>
<tr><td>SP Needle Driver</td><td>430006</td></tr>
<tr><td>SP Monopolar Curved Scissors</td><td>430004</td></tr>
<tr><td>SP Monopolar Cautery Instrument</td><td>430007</td></tr>
<tr><td>SP Fenestrated Bipolar Forceps</td><td>430011</td></tr>
</table>
</td></tr>
<tr><td>Common Name</td><td>Endoscope and accessories</td><td>IDENTICAL to the subject device</td></tr>
</table>

Characteristic	**Subject Device** *da Vinci SP Instruments with increased WRIST Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)* (K241814)	**Predicate Device** *da Vinci SP* Instruments (K240502)
Regulation Number	21 CFR 876.1500	**IDENTICAL** to the subject device
Product Code	NAY, GCJ	**IDENTICAL** to the subject device
Device Classification	Class II	**IDENTICAL** to the subject device
Classification Advisory Committee	General and Plastic Surgery	**IDENTICAL** to the subject device
System Compatibility	Compatible with the SP1098 system	**IDENTICAL** to the subject device

<table>
<tr><th>Characteristic</th><th>Subject Device

da Vinci SP Instruments with increased WRIST Range of Motion (ROM) (also referred to as “Enhanced Wrist” Instruments)

(K241814)</th><th>Predicate Device

da Vinci SP Instruments (K240502)</th></tr>
<tr><td>Number of Lives and Reprocessing Cycles</td><td>
<table>
<tr><th colspan="4">Subject Device SP Instruments</th></tr>
<tr><th>da Vinci SP Instruments with Enhanced WRIST Range of Motion (ROM)</th><th>da Vinci SP Instrument Model Numbers</th><th>Number of Lives</th><th>Number of Reprocessing Cycles</th></tr>
<tr><td>SP Maryland Bipolar Forceps</td><td>430152</td><td>25</td><td>38</td></tr>
<tr><td>SP Cadiere Forceps</td><td>430300</td><td>25</td><td>38</td></tr>
<tr><td>SP Needle Driver</td><td>430200</td><td>25</td><td>38</td></tr>
<tr><td>SP Monopolar Curved Scissors</td><td>430100</td><td>25</td><td>38</td></tr>
<tr><td>SP Monopolar Cautery Instrument</td><td>430101</td><td>25</td><td>38</td></tr>
<tr><td>SP Fenestrated Bipolar Forceps</td><td>430151</td><td>25</td><td>38</td></tr>
</table>
</td><td>
<table>
<tr><th colspan="4">Predicate Device SP Instruments (K240502)</th></tr>
<tr><th>da Vinci SP Standard Joggle Instruments</th><th>da Vinci SP Instrument Model Numbers</th><th>Number of Lives</th><th>Number of Reprocessing Cycles</th></tr>
<tr><td>SP Maryland Bipolar Forceps</td><td>430010</td><td>20</td><td>30</td></tr>
<tr><td>SP Cadiere Forceps</td><td>430009</td><td>22</td><td>33</td></tr>
<tr><td>SP Needle Driver</td><td>430006</td><td>22</td><td>33</td></tr>
<tr><td>SP Monopolar Curved Scissors</td><td>430004</td><td>20</td><td>30</td></tr>
<tr><td>SP Monopolar Cautery Instrument</td><td>430007</td><td>25</td><td>39</td></tr>
<tr><td>SP Fenestrated Bipolar Forceps</td><td>430011</td><td>20</td><td>30</td></tr>
</table>
</td></tr>
</table>

Characteristic	**Subject Device** *da Vinci SP Instruments with increased WRIST Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)* (K241814)	**Predicate Device** *da Vinci SP* Instruments (K240502)
Intended Use	**Intended Use:** ○ ***SP Maryland Bipolar Forceps***: The Maryland Bipolar Forceps is intended to be used with the *da Vinci SP* System for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels. ○ ***SP Cadiere Forceps:*** The Cadiere Forceps is intended to be used with the *da Vinci SP* System for dissecting, grasping, manipulating, and retracting tissues. The SP Cadiere Forceps is also intended for grasping and manipulating compatible bulldog clamps. ○ ***SP Needle Driver:*** The Needle Driver is intended to be used with the *da Vinci SP* System to drive needles through tissue and handle and tie suture. ○ ***SP Monopolar Curved Scissors:*** The Monopolar Curved Scissors with MCS Tip is intended to be used with the *da Vinci SP* System for manipulating, cutting, and dissecting tissue, coagulating and transecting tissue using monopolar electrosurgical energy, and cutting suture. ○ ***SP Monopolar Cautery Instrument***: The Monopolar Cautery Instrument with the 5 mm Cautery Hook Tip or 5 mm Cautery Spatula Tip is intended to be used with the *da Vinci SP* System for manipulating and dissecting tissue and coagulating and transecting tissue using monopolar electrosurgical energy. ○ ***SP Fenestrated Bipolar Forceps***: The Fenestrated Bipolar Forceps is intended to be used with the *da Vinci SP* System for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels. The SP Fenestrated Bipolar Forceps is also intended for grasping and manipulating compatible bulldog clamps.	**IDENTICAL** to the subject device

Indications for Use	<u>da Vinci SP Surgical System, Model SP1098:</u> 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 and general thoracoscopic 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. <u>EndoWrist SP Instruments:</u> 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 and general thoracoscopic 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.	**IDENTICAL** to the subject device

Characteristic	**Subject Device** *da Vinci SP Instruments with increased WRIST Range of Motion (ROM) (also referred to as "Enhanced Wrist" Instruments)* (K241814)	**Predicate Device** *da Vinci SP* Instruments (K240502)
Prescription use	Physician's use only	**IDENTICAL** to the subject device
Where used (hospital, home, ambulance, etc)	Hospital	**IDENTICAL** to the subject device
Principle of Operation	There are no changes to the Principle of Operation between the subject and predicate devices.	

Comparison of Predicate and Subject Device (*da Vinci SP Medium-Large Clip Applier)*

Table 9 includes a comparison of the subject device (*da Vinci SP* Medium-Large Clip Applier) and the predicate device (*da Vinci SP Medium-Large Clip Applier cleared via K240502*). Differences in the Characteristics as noted in ***Table 9*** are marked by ***GREYING OUT*** the specific rows. Additionally, any differences in the specific characteristics within these rows are ***BOLDED***.

Table 9: Comparison of Predicate and Subject Devices (*da Vinci SP Medium-Large Clip Applier)*

Characteristic	**Subject Device** *da Vinci SP Medium-Large Clip Applier* (K241814)	**Predicate Device** *da Vinci SP Medium-Large Clip Applier* (K240502)
General Information		
Manufacturer	Intuitive Surgical, Inc.	**IDENTICAL** to the subject device
Trade Name	*da Vinci SP* Medium-Large Clip Applier	**IDENTICAL** to the subject device
Model #	**430250**	**430005**
Common Name	Endoscope and accessories	**IDENTICAL** to the subject device
Regulation Number	21 CFR 876.1500	**IDENTICAL** to the subject device

Characteristic	Subject Device *da Vinci SP Medium-Large Clip Applier* (K241814)	Predicate Device *da Vinci SP Medium-Large Clip Applier* (K240502)
Product Code	NAY, GCJ	**IDENTICAL** to the subject device
Device Classification	Class II	**IDENTICAL** to the subject device
Classification Advisory Committee	General and Plastic Surgery	**IDENTICAL** to the subject device
System Compatibility	Compatible with the SP1098 system	**IDENTICAL** to the subject device
Intended Use	The Medium-Large Clip Applier is intended to be used with the *da Vinci SP* System for the application of compatible clips.	**IDENTICAL** to the subject device

Indications for Use	<u>da Vinci SP Surgical System, Model SP1098:</u> 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 and general thoracoscopic 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. <u>EndoWrist SP Instruments:</u> 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 and general thoracoscopic 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.	**IDENTICAL** to the subject device

Characteristic	Subject Device *da Vinci SP Medium-Large Clip Applier* (K241814)	Predicate Device *da Vinci SP Medium-Large Clip Applier* (K240502)
Prescription use	Physician's use only	**IDENTICAL** to the subject device
Number of Lives and Reprocessing Cycles	**Number of Lives: 150 closures** **Number of Reprocessing Cycles: 38**	**Number of Lives: 150 closures** **Number of Reprocessing Cycles: 39**
Where used (hospital, home, ambulance, etc)	Hospital	**IDENTICAL** to the subject device
Principle of Operation	There are no changes to the Principle of Operation between the subject and predicate device.	

Performance Data:

Performance test data (bench, animal, and cadaver tests) demonstrate that the subject device is substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness than the predicate device.

Bench Verifications

Testing was performed on the subject SP1098 Instruments (as listed in ***Table 1***) to verify that the design meets physical, mechanical, user interface, and equipment interface requirements. A summary of the bench verification testing for the SP1098 instruments is described in ***Table 10***.

Table 10: Summary of the bench verification testing for the SP1098 instruments

Subject Device	Testing
***da Vinci SP* Instruments**	Physical specifications (dimensions, weight, materials) Mechanical requirements (force, range of motion, accuracy) Equipment interfaces (mechanical, electrical, software) User interface and patient safety Re-use and reliability Environmental requirements Cleaning, Disinfection and Sterilization Shipping and storage Package and labeling

Cadaver and Animal Validations

Cadaver models were used to demonstrate clinical performance for anatomical access and reach for SP Instruments. Live animal models were used to assess safety and performance for SP Instruments in cases where a live tissue model was required. These models replicate factors experienced during clinical use, including working with perfused organs, bleeding, normal tissue handling, and ensuring that appropriate hemostasis is achieved and maintained. Procedures were chosen on the basis of the types of surgical tasks that are performed, and which SP instruments are needed for the tasks.

Human Factors

Human Factors process conducted for the subject devices included the following activities:

- Known use-related issues for predicate devices and devices similar to the subject devices were analyzed using post-market data and the MAUDE database. All identified use-related issues that are relevant to the use of the subject devices were documented in the risk analysis.
- A Comparative Task Analysis (CTA) was conducted to describe all aspects of the user-device interaction, through the breakdown of steps into user tasks, and to provide an analysis of comparison to the predicate for each task.
- A Use-Related Risk Analysis (URRA) was conducted to identify all use-related risks for each user task identified as New or Modified from the predicate in the CTA.
- Formative usability evaluations were conducted during the development process to inform the device user interface design and confirm assessment of use-related risks.

Summary:

Based on the intended use, indications for use, technological characteristics and performance data, the subject device(s), *da Vinci SP* Instruments are substantially equivalent to their respective predicate devices.