7 510(k) Summary (K170644)

This 510(k) applies to multiple instruments and accessories that have been cleared through a number of 510(k) Premarket Notifications. It concerns the Reprocessing Instructions provided to users for reprocessing of instruments and accessories intended for multiple usage. For ease of review, the subject devices have been listed in **Tables 7.1 and 7.2** (which is structured based on the device and the da Vinci Surgical System with which it is used). No changes have been made in the design or materials of the subject devices.

Table 7.1: Reusable Instruments used with the *da Vinci S/Si* (IS2000/IS3000) System

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086		
Contact	Kunal Gunjal Regulatory Affairs Specialist, Regulatory Affairs Phone Number: 408-523-8017 Fax Number: 408-523-8907 Email: Kunal.Gunjal@intusurg.com		
Date Summary Prepared	August 14, 2017		
Trade Name	*da Vinci S/ Si EndoWrist* Instruments (5mm & 8mm)	Harmonic ACE Curved Shears (5mm & 8mm)	*Endowrist* Stabilizer
Common Name	Endoscope and accessories	Endoscope and accessories	Cardiovascular Surgical Instrument
Classification	Class II, 21 CFR 876.1500	Class II, 21 CFR 876.1500	Class II, 21 CFR 876.1500
Product Codes	NAY	NAY	NAY
Classification Advisory Committee:	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Predicate Devices	K050369 (use with IS2000 Surgical System), with additional indications under K081137 (use with IS3000 System), K090993 (TORS indication) and K123329 (updated TORS indication)	K093217 (use with IS2000 and IS3000 Surgical Systems)	K060391 (use with IS2000 Surgical System K081137 (use with IS3000 System)

Table 7.2: Reusable Accessories used with the *da Vinci S/Si* (IS2000/IS3000) System

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086		
Contact	Kunal Gunjal Regulatory Affairs Specialist, Regulatory Affairs Phone Number: 408-523-8017 Fax Number: 408-523-8907 Email: Kunal.Gunjal@intusurg.com		
Date Summary Prepared	August 14, 2017		
Trade Name	*da Vinci S/ Si* Accessories	Flared Cannula (5mm & 8mm)	8.5 mm Endoscope Cannula and 8.5 mm Endoscope Alignment Target
Common Name	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500	Class II, 21 CFR 876.1500	Class II, 21 CFR 876.1500
Product Codes	NAY	NAY	NAY
Classification Advisory Committee:	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Predicate Devices	K050369 (use with IS2000 Surgical System), with additional indications under K081137 (use with IS3000 System), K090993 (TORS indication) and K123329 (updated TORS indication)	K101743 (use with IS2000 and IS3000 Surgical Systems)	K080155 (use with IS2000 Surgical System), with additional indications under K081137 (use with IS3000 System), K090993 (TORS indication) and K123329 (updated TORS indication)

Device Description

The *da Vinci* IS2000 (*S*) and IS3000 (*Si*) Surgical Systems are used in conjunction with reusable Instruments and Accessories to achieve their intended use. This 510(k) is submitted for changes to Reprocessing Instructions for all reusable *da Vinci S and da Vinci Si* Instruments and Accessories. **Tables 7.3 and 7.4** list the device descriptions for the subject devices impacted by the changes to the reprocessing instructions.

Table 7.3: Reusable Instruments used with the *da Vinci S/Si* (IS2000/IS3000) System

Trade Name	*da Vinci S/ Si EndoWrist* Instruments (5mm & 8mm)	Harmonic ACE Curved Shears (5mm & 8mm)	*Endowrist* Stabilizer
Device Description	S2000/IS3000 5mm and 8mm Instruments can be used only with the *da Vinci S* (IS2000) and *Si* (IS3000) Surgical Systems. Most instruments have a unique articulating design at their distal tips that mimics the human wrist. While seated at the Surgeon Console of the Surgical System, the surgeon can precisely control movements of the end effectors/instrument tips.	The Harmonic ACE Curved Shears Instrument (5mm/8mm) consists of a proximal reusable instrument housing and a distal disposable insert. The reusable instrument housing, when assembled with the disposable insert, is attached to the *da Vinci* IS2000/IS3000 System and delivers ultrasonic energy for transection (cutting) and coagulation of tissue.	The *Endowrist* Stabilizer is a reusable instrument similar to the *da Vinci S/ Si EndoWrist* Instruments. It is mounted on a PSM arm and is positioned, controlled, and held in place by the *da Vinci* IS2000/IS3000 System.

Table 7.4: Reusable Accessories used with the *da Vinci S/Si* (IS2000/IS3000) System

Trade Name	*da Vinci S/ Si* Accessories	Flared Cannula (5mm & 8mm)	8.5 mm Endoscope Cannula and 8.5 mm Endoscope Alignment Target
Device Description	*da Vinci S/ S*i Accessories mainly consist of: **Cannulae**, which are essentially hollow tubes that provide a path for instruments to access the surgical site **Obturators**, which provide a means of initially inserting the seal and cannula assemblies through the body wall by providing a fitted tip that extends beyond the cannula's most distal point. **"Other" Accessories** include PK Cables, instrument release kit (IRK), Blade Protectors and Insertion tools (used with the *Snap-Fit*™ Scalpel Instrument), a Blank Cartridge (used with the Endopass Delivery instrument), cannula mounts, light guide cable and cannula gage pins. These accessories have simple geometries with no long narrow lumens.	The Flared Cannula consists of a tapered hollow tubular shaft with a flared distal tip and a bowl with an integral electrical receptacle. The hollow shaft serves as the port of entry, the bowl is used to attach the cannula to the *da Vinci S/Si* Surgical System and the receptacle allows for attachment of commercially available dispersive electrode grounding pad via a 2-pin grounding connector.	The **8.5 mm Endoscope Cannula** is made of stainless steel components and is used to establish a port of entry for the 8.5mm Endoscope and provide an outlet for insufflation and/or smoke evacuation. The **Endoscope Alignment Target** is used during stereo endoscope set-up to align the left and right images from the endoscope to provide a stereo image to the console surgeon. It does not have any long narrow lumens.

Indications for Use:

Tables 7.5 through 7.7 list the Indications for Use for the devices impacted by the changes to the reprocessing instructions. There is no change in the Indications for Use between the subject and predicate devices.

Table 7.5: Reusable Instruments and Accessories used with the *da Vinci S/Si* (IS2000/IS3000) System

Trade Name	*da Vinci* S/ Si *EndoWrist* Instruments (5mm& 8mm) and Accessories	Harmonic ACE Curved Shears (5mm& 8mm)
Indications for Use	The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as TI and T2, and for benign base of tongue resection 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 (except for transoral otolaryngology surgical procedures). 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.	The Intuitive Surgical *da Vinci* Harmonic ACE™ Device is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the da Vinci Surgical Systems (Model IS1200, IS2000 and IS3000) and the Ethicon Endo-Surgery Generator 300 (Model GEN04) and Hand Piece (Model HP054).

Table 7.6: *EndoWrist* Stabilizer Instrument used with the *da Vinci S/Si* (IS2000/IS3000) System

Trade Name	*EndoWrist* Stabilizer Instrument- For use with the *da Vinci S* IS2000 System)	*EndoWrist* Stabilizer Instrument- For use with the *da Vinci Si* IS3000 System)
Indications for Use	The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pickups, needle holders, endoscopic retractors, stabilizers, 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 ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general noncardiovascular 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 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.	The Intuitive Surgical Endoscopic Instrument Control System (Intuitive Surgical® *da Vinci Si* Surgical System Model IS3000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, gynecological laparoscopic surgical procedures, general cardiovascular and non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system is indicated for adult and pediatric use. The system can also be employed, with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. 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.

Table 7.7: Flared Cannula (5mm & 8mm) used with the *da Vinci S/Si* (IS2000/IS3000) System

Trade Name	Flared Cannula (5mm & 8mm)
Indications for Use	The Flared Cannulae are intended to be used with the *da Vinci* Surgical System (*da Vinci S* (Model 1S2000) or *da Vinci Si* (Model 1S3000) to serve as a port of entry during *da Vinci* procedures that do not require maintenance of insufflation.

Technological Characteristics:

The technological characteristics of the subject devices are identical to the predicate devices.

Performance Data:

Performance test data demonstrates that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The testing conducted consisted of Cleaning Validations, Thermal Disinfection Validation and Human Factors Validation studies. Verification, design validation and biocompatibility testing were not repeated as the subject device design, materials, and manufacturing processes are identical to the predicate devices.

Cleaning Validation

The cleaning validation testing summarized in this submission validates the efficacy of the cleaning process in the Reprocessing Instructions in accordance with the following standards and guidance documents:

- FDA Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*, document issued on: March 17, 2015
- AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR 30: 2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Cleaning validation testing was performed using devices within the product family that represent the greatest challenge for the cleaning process. The Cleaning Efficacy test evaluated the cleaning process (as described in the Reprocessing Instructions) for the devices using qualitative visual inspection and quantitative endpoints.

Thermal Disinfection Validation

The disinfection validation testing summarized in this submission validates the efficacy of the disinfection process in the Reprocessing Instructions in accordance with the following guidance documents:

- FDA Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*, document issued on: March 17, 2015
- FDA Guidance, *"Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff"*, document issued on February 7, 2002.

Efficacy of the thermal disinfection process (as described in the Reprocessing Instructions) was performed using devices within the product family that represent significant challenges to the disinfection step within the scope of the intended use. The thermal disinfection efficacy testing evaluated the efficacy of the disinfection process in the Reprocessing Instructions using a quantitative endpoint i.e., 6-$\log_{10}$ reduction of typical vegetative organisms, such as Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives of the Klebsiella-Enterobacter group.

Human Factors Testing

The Reprocessing Instructions underwent a rigorous Human Factors testing process. This process included:

- Preliminary Evaluation: A preliminary evaluation was completed to better understand the users, uses, and use environment.
- Usability Risk Analysis (URA): Task and Use Error analysis was conducted for Reprocessing. This analysis included the process and Reprocessing Instructions.
- Design Team Participation: Human Factors Engineers participated in design meetings and played a significant role in the visual design and content development.
- Formative Testing: Formative tests were completed during the development of the new Reprocessing Instructions.
- Validation Testing: Validation test of representative Reprocessing Instructions was completed with representative end users.

This validation study assessed the usability, effectiveness, and use safety of the Reprocessing Instructions.

Summary:

Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject device is substantially equivalent and is as safe, as effective, and performs as well as the legally marketed predicate devices listed in **Tables 7.1 and 7.2.**