7 510(k) Summary (K170645)

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 **Table 7.1** (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 and Accessories used with the *da Vinci Xi* (IS4000) System

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086		
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Date Summary Prepared	August 14, 2017		
Trade Name	*da Vinci Xi EndoWrist* Instruments and Accessories	Monopolar and Bipolar Cautery Cord	*da Vinci Xi* Hasson Cone
Common Name	Endoscope and accessories	Monopolar/ Bipolar Electrosurgical Cord	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500	Class II, 21 CFR 878.4400	Class II, 21 CFR 876.1500
Product Codes	NAY, GCJ	GEI	GCJ
Classification Advisory Committee:	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Predicate Devices	K131861 (Clearance of *da Vinci Endowrist* Instruments and Accessories for use with the IS4000 system) K150284 (Addition of 6 additional instruments to the *da Vinci Xi* Instruments Family) K150837 (Addition of Small Clip Applier and Long Bipolar Grasper Instruments to the *da Vinci Xi* Instruments Family)	K133167	K153126

Device Description

The *da Vinci* IS4000 (*Xi*) Surgical Systems are used in conjunction with reusable *da Vinci* Instruments and Accessories to achieve their intended use. This 510(k) is submitted for changes to Reprocessing Instructions for all reusable *da Vinci Xi* Instruments and Accessories. **Table 7.2** lists the device descriptions for the subject devices impacted by the changes to the reprocessing instructions.

Table 7.2: Reusable Instruments and Accessories used with the *da Vinci Xi* (IS4000) System

Trade Name	*da Vinci Xi EndoWrist* Instruments	*da Vinci Xi* Accessories	Monopolar and Bipolar Cautery Cord	*da Vinci Xi* Hasson Cone
Device Description	The *da Vinci Xi EndoWrist* Instruments (8mm), have an articulating design at their distal tips that mimics the human wrist. Each instrument is used to perform one or more specific surgical tasks e.g., grasping, suturing, cutting, cauterizing, or tissue manipulation.	***da Vinci Xi* Accessories** mainly consists 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 an instrument release kit (IRK), an Insertion tool and Instrument introducer. These accessories have simple geometries with no long narrow lumens.	**The Monopolar and Bipolar Cautery Cords** are accessories to electrosurgical instruments where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery. The Monopolar and Bipolar Cautery Cords are insulated cords with an instrument-mating connector on one end and generator-mating connector on the other end.	The **Hasson Cone**, is a cone-shaped device which is intended to be used in endoscopic surgery to assist in establishing a port of entry through the abdominal wall for Intuitive Surgical *da Vinci Xi EndoWrist* Instruments, endoscopes, and compatible accessories. The Hasson Cone is available in two sizes; 8 mm and 12 mm & Stapler.

Indications for Use:

Table 7.3 lists 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 7.3: Reusable Instruments and Accessories used with the *da Vinci Xi* (IS4000) system

Trade Name	*da Vinci Xi EndoWrist* Instruments and Accessories	Monopolar and Bipolar Cautery Cords	*da Vinci Xi* Hasson Cone
Indications for Use	The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.	The Monopolar and Bipolar Cautery Cords are intended for connecting monopolar/bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency current from the electrosurgical generator to the surgical instrument.	The da Vinci Xi Hasson Cone has applications in laparoscopic surgery to establish a port of entry for *Intuitive Surgical da Vinci Xi EndoWrist* Instruments, endoscopes, or compatible accessories.

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. 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-log10 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 **Table7.1.**