DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 12, 2017

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

Re: K170875
Trade/Device Name: Da Vinci Si Single-Site Instruments and Accessories, Da Vinci Xi Single-Site Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: August 14, 2017
Received: August 15, 2017

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170875

Device Name
da Vinci Si Single-Site Instruments and Accessories

Indications for Use *(Describe)*

The Intuitive Surgical® da Vinci® Single-Site™ Instruments and Accessories used with the da Vinci® Si Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the da Vinci Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the Single-Site Port.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170875

Device Name
da Vinci Xi Single-Site Instruments and Accessories

Indications for Use *(Describe)*

The Intuitive Surgical da Vinci® Xi™ Single-Site Instruments and Accessories used with the da Vinci Xi Surgical System (IS4000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, suction/irrigation and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo oophorectomy with the da Vinci Xi Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, clip appliers, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, 8 mm endoscope cannula, flexible and rigid blunt obturators, cannula seal, and the Single-Site Port.

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.

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7 510(k) Summary (K170875)

This 510(k) applies to multiple instruments and accessories that have been cleared through previous 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 are 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 *da Vinci Si* (IS3000) *Single-Site* Instruments and Accessories

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 Si Single-Site* Instruments and Accessories
Common Name	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500
Product Codes	NAY, GCJ
Classification Advisory Committee:	General and Plastic Surgery
Predicate Devices	K122532 (use with IS3000 System) K130726 (Addition of Permanent Cautery Hook to the IS3000 *Single-Site* Instruments Family K141075 (Addition of Wristed Needle Driver to the IS3000 *Single-Site* Instruments Family)

Table 7.2: Reusable *da Vinci Xi* (IS4000) *Single-Site* Instruments and Accessories

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 Xi Single-Site* Instruments and Accessories
Common Name	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500
Product Codes	NAY, GCJ
Classification Advisory Committee:	General and Plastic Surgery
Predicate Devices	K152448

Device Description

The *da Vinci* IS3000 (*Si*) and IS4000 (*Xi*) Surgical Systems are used in conjunction with reusable *da Vinci Single-Site* Instruments and Accessories to achieve their intended use. This 510(k) is submitted for changes to Reprocessing Instructions for all reusable *da Vinci Si and Xi Single-Site* Instruments and Accessories.

Tables 7.3 to 7.6 list the device descriptions for the subject devices impacted by the changes to the reprocessing instructions.

Table 7.3: Reusable *da Vinci Si* (IS3000) *Single-Site* Instruments

Trade Name	*da Vinci Si Single-Site* Instruments
Device Description	The *da Vinci Single-Site* Instruments include instruments to perform grasping, cautery, cutting, clip ligation, suturing, and suction/irrigation functions. They are intended to be used with the IS3000 *da Vinci Si* Surgical System.

Table 7.4: Reusable *da Vinci Si* (IS3000) *Single-Site* Accessories

Trade Name	*da Vinci Si* Single-Site Accessories
Device Description	*da Vinci Si Single-Site* Accessories consist of fixed Shape Curved Cannulas (250mm and 300mm length), accessory cannulae for insertion of manual laparoscopic instruments, and semi-rigid blunt obturators (250mm and 300mm length).

Table 7.5: Reusable *da Vinci Xi* (IS4000) *Single-Site* Instruments

Trade Name	*da Vinci Xi Single-Site* Instruments
Device Description	The *da Vinci Xi Single-Site* Instruments enables single incision laparoscopic cholecystectomy, benign hysterectomy, and salpingo oophorectomy using the *da Vinci Xi* (IS4000) Surgical System.

Table 7.6: Reusable *da Vinci Xi* (IS4000) *Single-Site* Accessories

Trade Name	*da Vinci Xi Single-Site* Accessories
Device Description	The *da Vinci Xi Single-Site* Accessories include: 5mm Curved Cannulae, 5mm and 10mm straight cannulae, 8mm endoscope cannula, and flexible and rigid blunt obturators that enable single incision laparoscopic cholecystectomy, benign hysterectomy, and salpingo oophorectomy using the *da Vinci Xi* (IS4000) Surgical System.

Indications for Use:

Tables 7.7 to 7.8 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 7.7: Reusable *da Vinci Si* (IS3000) *Single-Site* Instruments and Accessories

Trade Name	*da Vinci Si Single-Site* Instruments and Accessories
Indications for Use	The Intuitive Surgical® *da Vinci*® *Single-Site*™ Instruments and Accessories used with the *da Vinci*® *Si* Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci* Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the Single-Site Port.

Table 7.8: Reusable *da Vinci Xi* (IS4000) *Single-Site* Instruments and Accessories

Trade Name	*da Vinci Xi Single-Site* Instruments and Accessories
Indications for Use	The Intuitive Surgical *da Vinci*® *Xi*™ *Single-Site* Instruments and Accessories used with the *da Vinci Xi* Surgical System (IS4000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, suction/irrigation and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo oophorectomy with the *da Vinci Xi Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, clip appliers, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, 8 mm endoscope cannula, flexible and rigid blunt obturators, cannula seal, and the Single-Site Port.

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, disinfection efficacy 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 **Tables 7.1 and 7.2.**