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 21, 2017

Intuitive Surgical, Inc.
Kunal Gunjal
Regulatory Affairs Specialist
1266 Kifer Road, Building 101
Sunnyvale, California 94086

Re: K170879
Trade/Device Name: IS4000 Stapler 45 Instrument and its Reusable Accessories, IS4000 EndoWrist Stapler 30 Instrument, IS3000 Stapler 45 Instrument and its Reusable Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ, GDW
Dated: August 24, 2017
Received: August 25, 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)*
K170879

Device Name
EndoWrist Stapler 45 Instrument and Accessories

Indications for Use *(Describe)*
The Intuitive Surgical EndoWrist® Stapler 45 System and Stapler 45 Reloads are intended to be used with the da Vinci Si Surgical System (Model 1S3000) for resection, transection and/or creation of anastomoses in General, Gynecologic, and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

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)*
K170879

Device Name
EndoWrist Stapler 45 Instrument and Accessories

Indications for Use *(Describe)*
The Intuitive Surgical EndoWrist Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with the da Vinci Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

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)

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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)*
K170879

Device Name
IS4000 EndoWrist Stapler 30 Instrument

Indications for Use *(Describe)*

The Intuitive Surgical EndoWrist® Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with the da Vinci Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device is indicated for adult and pediatric use. The devices can be used with staple line or tissue buttressing material.

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)

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510(k) Summary (K170879)

This 510(k) applies to *da Vinci Si and Xi* Stapler 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 **Table 1.1** (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 1.1: *da Vinci Si and Xi* Stapler 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	September 21, 2017		
Trade Name	*EndoWrist* Stapler 45 Instrument and Accessories	*IS4000 EndoWrist* Stapler 30 Instrument	*Endowrist* Stapler Instrument and Accessories
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
Classification Advisory Committee:	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Product Codes for Subject Devices (K170879)	NAY, GDW and GCJ	NAY and GDW	NAY and GDW
Product Codes for Predicate Devices	NAY, GDW and GCJ	NAY and GDW	NAY and GDW
Predicate Devices	K140553 (Clearance of Stapler 45 instrument and reusable accessories for use with the IS4000 system) K143217 (Addition of the 12mm & Stapler Bladeless Obturators for Use with the IS4000 System)	K152421 (Clearance of Stapler 30 instrument for use with the IS4000 system)	K113706 and K171388 (use with the IS3000 system)

Device Description

Table 1.2 lists the device descriptions for the subject devices impacted by the changes to the reprocessing instructions.

Table 1.2: *da Vinci Si and Xi* Stapler Instruments and Accessories

Trade Name	*Endowrist* Stapler Instrument (used with the IS3000 System)	*EndoWrist* Stapler 45 Instrument (used with the IS4000 system)	*IS4000 EndoWrist* Stapler 30 Instrument (used with the IS4000 system)	*EndoWrist* Stapler Accessories (used with the IS3000 system)	*EndoWrist* Stapler 45 Accessories (used with the IS4000 system)
Device Description	*The Endowrist* Stapler Instrument, when used with the compatible Stapler 45 Reloads, delivers multiple rows of staples and transects the tissue along the middle of the staple line. The *Endowrist* Stapler Instrument is a reusable device while the Stapler 45 reloads (available in various sizes) are single-use/disposable devices.	The *EndoWrist* Stapler 45 Instrument is intended for resection, transection, and/or creation of anastomoses in surgery by placing multiple staggered rows of implantable staples in the target tissues (stapling) followed by cutting of the target tissue along the middle of the staple line (transection).	*IS4000 EndoWrist* Stapler 30 Instrument is intended for resection, transection, and/or creation of anastomoses in surgery by placing multiple staggered rows of implantable staples in the target tissues (stapling) followed by cutting of the target tissue along the middle of the staple line (transection). The Stapler 30 Instrument is a reusable, fully wristed articulating device offered in two configurations, a straight tip and a curved-tip.	*EndoWrist* Stapler Reusable Accessories consist of a Stapler Cable, Stapler Release Kit, Stapler Cannula, Blunt Obturator, Stapler Cannula Reducer, and Stapler Motor Pack (SMP).	***EndoWrist* Stapler 45 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 the SRK (Stapler Release Kit).

Indications for Use:

Table 1.3 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 1.3: *da Vinci Si and Xi* Stapler Instruments and Accessories

Trade Name	*Endowrist* Stapler and its reusable Accessories	*EndoWrist* Stapler 45 Instrument and Accessories	*IS4000 EndoWrist* Stapler 30 Instrument
Indications for Use	The Intuitive Surgical *EndoWrist*® Stapler 45 System and Stapler 45 Reloads are intended to be used with the *da Vinci Si* Surgical System (Model 1S3000) for resection, transection and/or creation of anastomoses in General, Gynecologic, and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).	The Intuitive Surgical *EndoWrist* Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with the *da Vinci* Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).	The Intuitive Surgical *EndoWrist*® Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with the *da Vinci* Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device is indicated for adult and pediatric use. The devices can be used with staple line or tissue buttressing material.

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.

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 **Table 1.1.**