DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 15, 2015

Intuitive Surgical Incorporated
Ms. Sarah Rizk
Senior Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, Califiornia 94086

Re: K150284
Trade/Device Name: IS4000 da Vinci EndoWrist® Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: April 14, 2015
Received: April 15, 2015

Dear Ms. Rizk:

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 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" (21CFR 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 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 yours,

Jennifer R. Stevenson -S

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)*

K150284

Device Name
IS4000 da Vinci EndoWrist® Instruments

Indications for Use *(Describe)*

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model 1S4000) 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.

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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary

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

Contact: Sarah Rizk
Regulatory Affairs
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Date Summary Prepared: Feb 4, 2015

Trade Name: IS4000 *da Vinci EndoWrist*® Instruments

Common Name: Endoscope and accessories

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Codes: NAY, GCJ

Classification Advisory Committee: General and Plastic Surgery

Predicate Device: K131861 – IS4000 *da Vinci* Surgical System

Device Description

The subject IS4000 *da Vinci EndoWrist* Instruments are to be used with the IS4000 *da Vinci* Surgical System. The *EndoWrist* Instruments consist of the housing, shaft, wrist, and tip. The housing contains the connection mechanism to the IS4000 *da Vinci* Surgical System arm. The shaft and wrist allow for different axes of rotation, and the instrument tip is used to interact with the patient tissue. These instruments are reusable and provided non-sterile. The six subject IS4000 *EndoWrist* Instruments are:

Name	Part No.
Needle Drivers	
8 mm Mega Needle Driver	470194
8 mm Large SutureCut Needle Driver	470296
Graspers	
8 mm Cadiere Forceps	470049

Name	Part No.
8 mm Cobra Grasper	470190
8 mm DeBakey Forceps	470036
Scissors	
8mm Round Tip Scissors	470007

Intended Use/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.

Substantial Equivalence:

The subject IS4000 *da Vinci EndoWrist* Instruments are very similar to the predicate devices (IS4000 *da Vinci EndoWrist* Instruments in K131861). They have the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device. Modifications consist of geometrical changes to instrument tips to provide an assortment of distal tips and offer more options for grasping, dissecting, manipulating, and transecting tissue for surgeon preference.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of modifications to the predicate instruments. Design verification and design validation testing were conducted on the subject instruments to confirm that the design outputs meet design input requirements and that each instrument is safe and effective for its intended use.

Design Verification:
The bench testing with the subject *EndoWrist* Instruments was performed on an IS4000 *da Vinci* Surgical System. The general and instrument-specific design verification summarized in this submission verifies mechanical and labeling requirements for the subject instruments, such as:

- instrument reliability and durability,
- leakage,
- roll, pitch, and yaw range of motion,
- jaw close and open positions,
- friction,
- torque,
- instrument insertion
- adequacy of labeling.

Other verification performed includes software compatibility testing and instrument data verification testing to confirm the subject *EndoWrist* instruments function as intended with the current production IS4000 System software.

Design Validation:
The design validation summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject *EndoWrist* Instruments. Design validations for each subject *EndoWrist* Instrument address how the features of the instrument meet the user needs and intended use as documented in the product requirements documents. The safety and efficacy of the instruments was assessed in representative simulated clinical settings that utilized porcine (*in vivo*) and cadaveric tissue models to evaluate applicable requirements through normal and expected worst case clinical use. Representative tissue types were used, as appropriate, for evaluating applicable requirements.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject IS4000 *da Vinci EndoWrist* Instruments are substantially equivalent to the predicate IS4000 *da Vinci EndoWrist* Instruments cleared in K131861.