DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 9, 2016

Intuitive Surgical, Inc.
Ms. Melissa Gonzales
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, CA 94086

Re: K152448
Trade/Device Name: 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: February 5, 2016
Received: February 8, 2016

Dear Ms. Gonzales:

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 -A

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)*
K152448

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, 8mm 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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510(k) Summary

510(k) Owner: Intuitive Surgical, Inc.
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Contact: Melissa S. Gonzalez
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Date Summary Prepared: August 26, 2015

Trade Name: *da Vinci*® *Xi*™ Single-Site Instruments and Accessories

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: K122532 – *da Vinci*® *Si*™ Single-Site Instruments and Accessories

Device Description

The *da Vinci Xi* Single-Site Instruments and Accessories are a set of devices developed by Intuitive Surgical to enable single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo oophorectomy using the *da Vinci Xi* (IS4000) Surgical System.

Intended Use/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.

Substantial Equivalence:

The subject *da Vinci Xi* Single-Site Instruments and Accessories are very similar to the predicate devices (*da Vinci*® *Si*™ Single-Site Instruments and Accessories in K122532). They have the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device. The basic architecture of the subject devices remains unchanged from the predicate; the distal tips (jaws, blades, cautery-tips, and clevis) of the *da Vinci Xi* Single-Site Instruments are identical to the predicate *da Vinci Si* Single-Site Instruments. However, the back ends of the instruments and accessories have been modified for compatibility with the IS4000 Surgical System, incorporating elements of both the predicate *da Vinci Si* Single-Site Instruments and Accessories and the referenced IS4000 8mm *EndoWrist* Instruments and related accessories. Several previously cleared accessories, used with both the subject and the predicate devices, are unchanged from the predicate *da Vinci Si* Single-Site Accessories (10mm accessory cannula and obturator and 5mm flexible blunt obturators).

Performance Data:

In accordance with Intuitive Surgical's Design Control process, risk analyses were 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 the design input requirements and that each instrument is safe and effective for its intended use.

Design Verification:

The bench testing with the subject *da Vinci Xi* Single-Site Instruments and Accessories was performed with an IS4000 *da Vinci* Surgical System. The general and device-specific design verification summarized in this submission verifies mechanical and labeling requirements for the subject device, such as:

- Instruments:
  - Physical specifications (size, weight, shape);
  - Mechanical requirements (axes torques, loading, range of motion, accuracy, grip forces, needle handling, tip alignment):
  - Electrical requirements;
  - User interface;
  - Equipment interfaces (cannula, sterile adapter, RFID, Universal Surgical Manipulator, Patient Side Manipulator).
- Accessories:
  - Physical specifications (size, shape, finish, materials);
  - Mechanical requirements (forces, loading, insufflation, flow rate, cannula insertion, port insertion/removal);
  - Compatibility (instruments, seals, cannulae)
  - Markings
  - System Recognition (magnets)

Other verification included software compatibility testing and instrument data verification testing to confirm the subject *da Vinci Xi* Single-Site Instruments and Accessories function as intended.

Design Validation:

The design validation summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject *da Vinci Xi* Single-Site Instruments and Accessories. Design validations for each subject *da Vinci Xi* Single-Site Instrument and Accessory address how the features of each device 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 *da Vinci Xi* Single-Site Instruments and Accessories are substantially equivalent to the predicate *da Vinci Si* Single-Site Instruments and Accessories cleared in K122532.