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

December 10, 2014

Intuitive Surgical Incorporated
Ms. Crystal Ong
Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K142683
Trade/Device Name: 12mm Endoscope and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, KCT
Dated: September 18, 2014
Received: September 19, 2014

Dear Ms. Ong:

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,

David Krause -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)*
K142683

Device Name
12 mm Endoscope and Accessories

Indications for Use *(Describe)*
The 12 mm Endoscope is intended to provide real-time, 3D, high-definition imaging enabling surgeons to perform minimally invasive surgery.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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

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)*
K142683

Device Name
12 mm Endoscope Sterilization Tray

Indications for Use *(Describe)*
The Intuitive Surgical 12 mm Endoscope Sterilization Tray is intended for use to encase and protect da Vinci Xi endoscopes (Model #'s 951246 and 951247) for sterilization in any of the following sterilization machines/ cycles:

- STERRAD 100NX sterilization system using the Express cycle
- STERRAD 100S sterilization system using the Standard cycle
- Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles
- Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles
- Steris V-PRO 1 using the V-PRO cycle

The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one da Vinci Xi Endoscope. The maximum weight of tray and endoscope is 11.0 lbs. The Intuitive Surgical Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD and Steris compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.

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

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Crystal Ong Regulatory Affairs Phone Number: 408-523-8636 Fax Number: 408-523-8907 Email: crystal.ong@intusurg.com
Date Summary Prepared:	September 18, 2014
Trade Name:	*da Vinci*® *Xi* (IS4000) 12 mm Endoscope and Accessories
Common Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument) KCT (Sterilization Wrap)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	*da Vinci*® *Xi* Surgical System device, K131861 *EndoWrist*® Stapler 45, Stapler 45 Reloads,K140553 *Intuitive Surgical* Endoscope Sterilization Tray, K133942

Device Description

The Intuitive Surgical *da Vinci*® *Xi* (IS4000) 12 mm Endoscope and Accessories use the existing endoscopic imaging system submitted in K131861 (cleared March 28, 2014). The 12 mm rigid endoscopes come in both 0° and 30° angles for use through 12 mm ports.

Entry to the body cavity and maintenance of pneumoperitoneum are facilitated through the use of a12 mm & Stapler cannulae (both standard and long lengths), blunt obturators (also in standard and long lengths) and the 12 mm & Stapler Cannula Seal.

The Endoscope Sterilization Tray (an accessory to the 12 mm endoscope) is a thermoformed plastic tray with silicone inserts, a plastic lid, and a stainless steel cover. The tray, lid, and cover contain perforations to allow sterilization gases to penetrate the tray and sterilize the endoscope. The Endoscope Sterilization Tray is designed to encase and protect *da Vinci* 12 mm endoscopes during transport and sterilization. The tray is compatible with the STERRAD 100S, STERRAD 100NX Express and Steris V-Pro sterilization systems.

Intended Use/Indications for Use:

The 12 mm Endoscope is intended to provide real-time, 3D, high-definition imaging enabling surgeons to perform minimally invasive surgery.

The intended use for the 12 mm & Stapler Accessories is unchanged from what was cleared in K140553 (*EndoWrist*® Stapler 45, Stapler 45 Reloads). They are being submitted again in this 510(k) to clear them for use with the subject device, *da Vinci*® *Xi* (IS4000) 12 mm Endoscope.

The indications for use for the 12 mm Endoscope Sterilization Tray is a modification of the indication statement for the Endoscope Sterilization Tray (K133942). The model numbers for the 12 mm Endoscope have been added. Steris V-Pro was also validated and therefore added to the indication statement. Finally, the maximum weight of the tray and endoscope has been adjusted to reflect the weight of the modified subject devices. The resulting indications for use for the 12 mm Endoscope Sterilization Tray are as follows:

> The Intuitive Surgical 12 mm Endoscope Sterilization Tray is intended for use to encase and protect *da Vinci Xi* endoscopes (Model #'s 951246 and 951247) for sterilization in any of the following sterilization machines/cycles:
>
> • STERRAD 100NX sterilization system using the Express cycle
>
> • STERRAD 100S sterilization system using the Standard cycle
>
> • Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles
>
> • Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles
>
> • Steris V-PRO 1 using the V-PRO cycle
>
> The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one *da Vinci Xi* Endoscope. The maximum weight of tray and endoscope is 11.0 lbs. The Intuitive Surgical Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD and Steris compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.

Technological Characteristics:

In terms of intended use, indications for use, and technological characteristics, the *da Vinci*® *Xi* (IS4000) 12 mm Endoscope and Accessories are substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device, cleared under K131861, *EndoWrist*® Stapler 45, Stapler 45 Reloads cleared under K140553, and the *Intuitive Surgical* Endoscope Sterilization Tray, cleared under K133942.

Performance Data:

Performance test data (bench and animal tests) demonstrate that the subject device is substantially equivalent to the predicate devices and that the design output meets the design input

requirements for the *da Vinci*® *Xi* (IS4000) 12 mm Endoscopes. The testing conducted consisted of design verification, reliability and animal testing.

Design Verification:

The testing provided in this submission consisted of dimensional measurements, mechanical, and functional verification.

Test	Summary
Design Verification, 12 mm Endoscope – All final tests PASSED	The purpose of this test was to verify that the endoscopes met the dimensional, mechanical, functional, and electrical requirements and specifications. Test methods were based on pre-defined test procedures, and objective pass/fail criteria were defined in the protocol and used. Sample sizes up to six units were used. The following design verification tests were performed: - Illumination - Mechanical - Electrical - Equipment Interface - Cleaning and Sterilization - Labeling
Design Verification, 12 mm Endoscope Sterilization Tray – All final tests PASSED	The purpose of this test was to verify that the 12 mm Endoscope Sterilization Tray met the dimensional, functional, and labeling requirements. Test methods were based on pre-defined test procedures, and objective pass/fail criteria were defined in the protocol and used. Sample sizes up to four units were used.

Reliability:

The testing provided in this submission consisted of simulated use cycling test articles through their typical use environment, including sterilization. The evaluation method included visual inspections as well as functional testing.

Test	Summary
Design Verification, Life, 12 mm Endoscope – All final tests PASSED	The purpose of this test was to verify that the endoscopes were robust when exposed to a typical use environment. A sample size of nine was used. Test articles were cycled through Simulated clinical use including the following: - Visual Inspection - Mechanical Stressing - RFID Functional Test - Stereo Vision Test - Simulated Use - Clean - Sterilize
Design Verification, 12 mm Endoscope STERRAD 100S Compatibility—All final tests PASSED	The purpose of this test was to compare the material effects of STERRAD 100NX Express Cycle to the material effects of the STERRAD 100S Cycle on the 12 mm endoscope. A visual inspection of certain sites on the endoscope (different materials) was performed before and after sterilization cycling. Functional testing was also performed to confirm that the test article successfully survived sterilization cycling.
Design Verification, 12 mm Endoscope Steris V-Pro maX Compatibility—All final tests PASSED	The purpose of this test was to compare the material effects of STERRAD 100NX Express Cycle to the material effects of the Steris V-Pro maX on the 12 mm endoscope. A visual inspection of certain sites on the endoscope (different materials) was performed before and after sterilization cycling. Functional testing was also performed to confirm that the test article successfully survived sterilization cycling.

Animal Testing:

The testing provided in this submission was performed using simulated clinical models (animal) to evaluate the performance of the *da Vinci Xi* (IS4000) 12 mm Endoscope. This included design validation to confirm that the device meets the user needs and intended use, comparison testing against the predicate device (IS4000 8 mm Endoscope), and surgeon evaluations.

Test	Summary
Design Validation – All final tests PASSED	The purpose of this testing was to confirm that the *da Vinci Xi* (IS4000) 12 mm Endoscope meets the user needs and intended use as documented in the Product Requirements document. Testing was completed across three labs conducted with three porcine. A variety of surgical tasks were completed to evaluate the 12 mm Endoscope's vision characteristics. Test methods were based on pre-defined test procedures and objective pass/fail criteria were defined in the protocol and used.
Device Comparison – All final tests PASSED	This testing compared the basic clinical function of the *da Vinci Xi* (IS4000) 12 mm Endoscope with respect to the predicate device (IS4000 8 mm Endoscope). The study was a side-by-side comparison of the *da Vinci Xi* (IS4000) 12 mm Endoscope to the predicate device (IS4000 8 mm Endoscope). Two porcine were used in a pelvic, an upper GI, and a kidney setup to complete various visualization tasks for each device.
Surgeon Evaluation – All final tests PASSED	The purpose of this testing was to confirm that the *da Vinci Xi* (IS4000) 12 mm Endoscope has clinically acceptable performance and allows for safe and effective surgical use as assessed by independent, external surgeon evaluators. Testing was completed across three labs, utilizing canines or porcine. Six independent, external surgeons served as evaluators to complete the vision assessments. All evaluators found each vision criteria clinically acceptable and safe for the subject device.

Human Factors and Usability Testing:

Summative usability validation studies were conducted with users (surgeons and operating room staff) for the *da Vinci® Xi* Surgical System (K131861). These studies were conducted with the predicate endoscopes in a simulated operating room and involved typical workflow scenarios as well as certain troubleshooting scenarios related to safety-critical tasks. With the exception of a separable light guide, the work-flow with the subject device is unchanged from the previously evaluated predicate device.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the *da Vinci*® *Xi* (IS4000) 12 mm Endoscope and Accessories are substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device, cleared under K131861, *EndoWrist*® Stapler 45, Stapler 45 Reloads cleared under K140553, and the *Intuitive Surgical* Endoscope Sterilization Tray, cleared under K133942.