



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

April 29, 2016

Intuitive Surgical
Ms. Crystal Ong
Sr. Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K152892

Trade/Device Name: da Vinci Xi Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: March 29, 2016
Received: March 30, 2016

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,


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

Indications for Use

510(k) Number (if known)
K152892

Device Name
da Vinci Xi Surgical System

Indications for Use (Describe)

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi 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.

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.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Crystal Ong
Regulatory Affairs
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Date Summary Prepared: April 29, 2016

Trade Name: da Vinci® Xi Surgical System

Common Name: System, Surgical, Computer Controlled Instrument

Classification: Class II - 21 CFR 876.1500, Endoscope and Accessories

Product Codes: NAY, GCJ

Classification Advisory Committee: General and Plastic Surgery

Predicate Device: K131861 – da Vinci® Xi Surgical System

Device Description

The subject da Vinci® Xi™ Surgical System (Model IS4000) with the Integrated ESU (IESU) feature has the same design and components as the predicate da Vinci® Xi™ Surgical System, with a software modification to enable communication between the Surgeon Console (Model SS4000) and the ERBE ESU Model VIO dV mounted on the Vision Cart. Software changes to the ERBE ESU Model VIO dV that enable communication with the da Vinci Xi Surgical System (Model IS4000) have been submitted to FDA under K150364.

Intended Use/Indications for Use:

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi 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 cardiomy 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 device, *da Vinci Xi* Surgical System with the Integrated ESU feature, has the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device. The only technological difference is that the subject device can now control the settings on the ERBE ESU Model VIO dV instead of requiring the Patient Side Assistant to change the settings on the ESU.

Performance Data:

In accordance with Intuitive Surgical's Design Control process, risk analysis was conducted to evaluate the impact of the modification to the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design outputs meet the design input requirements and that the subject device is safe and effective for its intended use.

Design Verification:

Software verification testing was performed for the Surgeon Side Cart (SSC) - Vision Cart (VSC) user interface and for the integrated instrument function control sub-system to confirm that the subject *da Vinci Xi* Surgical System with the Integrated ESU feature functions as intended.

Design Validation:

The design validation testing was performed to confirm that the *da Vinci Xi* Surgical System, Model IS4000 with P4 system software met the user needs and intended use as documented in the Product Requirements document. Included as part of that evaluation were test cases specific to the software-enabled Integrated ESU control. The portion of testing that evaluated control of the Integrated ESU was evaluated using a tissue model.

Human Factors

A comprehensive human factors engineering (HFE) process was followed for the development of the *da Vinci Xi* Surgical System with the Integrated ESU feature. A summative usability validation study was conducted to demonstrate that the device can be used to perform essential functions and is safe and effective for its intended use. The results of the validation study and the other elements of the HFE program provide evidence that changing IESU settings from the

surgeon console is safe and effective when used by the intended users in the intended use environments and in the foreseeable use scenarios.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject *da Vinci Xi* Surgical System with the Integrated ESU feature is substantially equivalent to the predicate *da Vinci Xi* Surgical System cleared in K131861.