



Food and Drug Administration
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July 11, 2016

Intuitive Surgical, Inc.
Mr. Brandon Hansen
Project Manager, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K161271
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
Dated: June 20, 2016
Received: June 21, 2016

Dear Mr. Hansen:

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" (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 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) <div style="border: 1px solid black; padding: 2px; text-align: center;">K161271</div>	
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 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.	
Type of Use (Select one or both, as applicable) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K161271

510(k) Summary

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

Contact: Brandon Hansen
Regulatory Affairs
Phone Number: 408-523-7485
Fax Number: 408-523-8907
Email: brandon.hansen@intusurg.com

Date Summary Prepared: May 4, 2016

Trade Name: *da Vinci® Xi™* Surgical System

Common Name: Endoscopic instrument control system

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Codes: NAY (System, Surgical, Computer Controlled Instrument)

Classification Advisory Committee: General and Plastic Surgery

Predicate Device: *da Vinci® Xi™* Surgical System device, K131861

Device Description

Remote Software Update is a software enabled feature that performs software update downloads and installations without the need of a service engineer to be physically at the user's site. Remote Software Update utilizes the OnSite functions of the *da Vinci® Xi™* Surgical System to facilitate and manage software updates.

The software update is downloaded over a network connection using secure communication protocols. Once the software update package is downloaded and cryptographically verified with a digital signature, metadata inside the package determines the type of installation required and if necessary guides the user through all of the steps required to complete the software update.

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 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.

Technological Characteristics:

In terms of intended use, indications for use, and technological characteristics, the *da Vinci Xi Surgical System with Remote Software Update* is substantially equivalent to the currently marketed *da Vinci Xi Surgical System* device, cleared under K131861.

Performance Data:

Performance test data demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. Software testing was conducted to support this modification.

The software testing included user interface, algorithm, and software verification testing.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the *da Vinci Xi Surgical System with Remote Software Update* is substantially equivalent to the currently marketed *da Vinci Xi Surgical System* device, cleared under K131861.