



Food and Drug Administration
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January 15, 2016

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

Re: K151794

Trade/Device Name: da Vinci Xi Surgical System with Table Motion
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: December 29, 2015
Received: December 30, 2015

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" (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.
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510(k) Number (if known)

K151794

Device Name

da Vinci Xi Surgical System with Table Motion

Indications for Use (Describe)

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 for in the Professional Instructions for Use.

da Vinci Table Motion is intended to allow the surgical staff to reposition the patient by adjusting the table without undocking the da Vinci Xi Surgical System during urologic surgical procedures, general laparoscopic surgical procedures, and gynecologic laparoscopic surgical procedures. It is designed to be used with a compatible OR table.

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:	Brandon Hansen Regulatory Affairs Phone Number: 408-523-7485 Fax Number: 408-523-8907 Email: brandon.hansen@intusurg.com
Date Summary Prepared:	January 13, 2016
Trade Name:	da Vinci® Xi Surgical System with Table Motion
Common Name:	Endoscopic instrument control system, endoscopic instruments and accessories
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

da Vinci Table Motion is a software-enabled feature for the da Vinci Xi Surgical System. da Vinci Table Motion allows the surgical team to reposition the patient by adjusting the operating table synchronously with, but without undocking from, the Xi surgical system. Communication between the system and the table is established through IR and RF wireless signals. There is also a wired configuration if wireless is not available.

All motion commands entered by the user on the table remote control are re-directed through the da Vinci Xi system for authorization. When paired, all table remote control button presses, instead of being sent directly from the remote control to the table motion controller in the table, are forwarded to the da Vinci Xi for approval. When the da Vinci Xi determines that the system is in a safe state for table motion to occur, the button request is forwarded to the table motion controller, and motion may then occur.

To enter *da Vinci* Table Motion, all instrument tips must be in view and under active control by the surgeon at the console; instruments not under active surgeon control must be removed and the table feet must be locked before the system will allow table motion.

During Table Motion, the *da Vinci* Xi system monitors the positioning and velocity of the Trumpf Medical TS7000dV Operating Room Table. The setup joint (SUJ) brakes release and allow the arms to passively follow table movements. The setup structure and boom actively move with the table as needed to maintain relative positioning of the remote center of each arm.

Audio and visual messaging is used to guide the user during table motion. Audio cues consist of tones and voice prompts. Visual messaging on the surgeon display, vision cart touchscreen, and table remote control, informs users of table motion status. The vision cart touchscreen display includes a tabbed interface that allows the user to adjust certain system settings, view and recover from system fault conditions, and view instructions.

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 cardiectomy 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.

da Vinci Table Motion is intended to allow the surgical staff to reposition the patient by adjusting the table without undocking the *da Vinci* Xi Surgical System during urologic surgical procedures, general laparoscopic surgical procedures, and gynecologic laparoscopic surgical procedures. It is designed to be used with a compatible OR table.

Technological Characteristics:

In terms of intended use, indications for use, and technological characteristics, the *da Vinci* Xi Surgical System with Table Motion 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. The testing conducted consisted of software, electrical safety, EMC, human factors and simulated use in animal models.

The software testing included user interface, algorithm and software verification testing. Electrical safety and EMC testing were conducted by outside labs and in conformance to recognized standards. Multiple clinical validation studies were conducted using animal, cadaver and inanimate models. This testing included actual surgical procedures from the three surgical specialties in the indications for use statement. External surgeons were used for a portion of this testing. The clinical validation testing demonstrated clinically acceptable performance of the *da Vinci Xi Surgical System with Table Motion* and substantial equivalence to the predicate *da Vinci Xi Surgical System*.

Simulated use testing consisted of design validation testing using clinical engineers and surgeon evaluation studies using external surgeons. Design Validation testing by clinical engineers was completed across three labs utilizing one porcine model, one cadaver, and dry/inanimate models. The porcine model was used for test cases requiring live tissue interaction (such as for port site retention and trauma assessment). The cadaver was used for those test cases that required realistic human anatomy, such as for patient positioning and access and patient clearance. Inanimate models were used for those interactions that occur before or after surgery for those features and mitigations that do not affect system surgical use. Tests cases were grouped into the following categories: pairing and basic functionality, intraoperative table motion, surgical performance, foreseeable clinical misuse, egress and transport and user interactions. The *da Vinci Xi Surgical System with Table Motion* successfully passed all test cases. Furthermore, this testing identified no issues of safety or effectiveness and no new risks.

Surgeon evaluation testing was completed across six labs, utilizing porcines and cadavers. The porcine model was used to assess whether the IOTM method is at least as safe as the current manual method of table motion. Different procedural tasks, corresponding with changes in patient positions, formed the basis of comparison between the manual and the IOTM (subject device) method. The cadaver model was used to confirm the ability to complete surgical procedures, the ability to adequately expose tissues and organs, and the ability to maintain adequate external clearance while using IOTM. Different procedures (and target anatomies), corresponding with changes in patient positions, facilitated evaluation of the testers' ability to complete these procedures while using ITOM. Six independent, external surgeons, representing four different surgical specialties (Gynecological Oncology, Urology, Colorectal, and General Surgery), served as evaluators for the comparative assessments. Upon completion of testing, surgeon evaluators graded the safety and efficacy of performing surgery using intraoperative table motion for both the porcine and cadaveric evaluations. A Likert score (scaled from one to

five, where a score of three was considered passing) was assigned for each of the attributes. The *da Vinci Xi Surgical System with Table Motion* successfully passed all requirements as described in the protocol. All surgeons found that the IOTM method is at least as safe as the current manual method of table motion (i.e., scored 3 or above). In addition, with an average Likert score of 4.7 or higher, surgeons confirmed the ability to complete surgical procedures, the ability to adequately expose tissues and organs, and the ability to maintain adequate external clearance while using IOTM.

Human Factors and Usability Testing:

The Human Factor engineering process, culminating in usability validation studies, was utilized to identify and assess the use-related risks associated with *da Vinci Xi Surgical System with Table Motion*. The safety and usability of the *da Vinci Xi Surgical System with Table Motion* was assessed to ensure residual risk is at acceptable levels, and that the use-safety of the system has not diminished in comparison to the non-integrated process of moving the operating table during *da Vinci* surgeries. Two summative usability validation studies were conducted with users (surgeons, operating room staff, and anesthesiologists) for the *da Vinci Xi Surgical System with Table Motion*. A simulated OR environment including equipment and sound provided realistic conditions for the testing. The studies involved typical workflow scenarios, as well as certain troubleshooting scenarios related to safety-critical tasks.

A minimum of fifteen surgical teams with surgeons from different surgical specialties (urology, gynecology, general surgery and colorectal) participated in each summative study. A surgeon, operating staff, and an anesthesiologist comprised a surgical team. Each participant received hands-on training prior to conducting testing. Users performed essential tasks including identification of compatible equipment, pairing of system and table, activating table motion, moving the table using the table remote, and troubleshooting scenarios. Data collected included both objective performance data and subjective feedback from participants. Objective performance data included observations of users' ability to complete tasks, use-errors, close calls, and any difficulties encountered. Subjective feedback included open-ended questions about risks and safety, multiple choice ratings, and follow-up interviews. Results of the validation studies and the other elements of the human factors engineering program provided evidence that the *da Vinci Xi Surgical System with Table Motion* is safe and effective when used by the intended users in the intended use environment. .

Summary:

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