



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 28, 2017

Intuitive Surgical, Inc.
% Ms. Cindy Domecus
Principal, Domecus Consulting Services, LLC &
Chief Regulatory Advisor, Intuitive Surgical
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K171699

Trade/Device Name: da Vinci Xi Surgical System, da Vinci Si Surgical System, da Vinci X
Surgical System

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: Class II

Product Code: NAY

Dated: June 7, 2017

Received: June 8, 2017

Dear Cindy Domecus:

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,

**Jennifer R.
Stevenson -S3**

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)

K171699

Device Name

da Vinci Surgical System, Model IS4000, and EndoWrist Instruments and Accessories

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 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.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

Device Name

da Vinci Surgical System, Model IS3000, and EndoWrist Instruments and Accessories

Indications for Use (Describe)

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System Model IS3000) 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, 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.

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Indications for Use

510(k) Number (if known)

Device Name

da Vinci Surgical System, Model IS4200, and EndoWrist Instruments and Accessories

Indications for Use (Describe)

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS4200) 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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Special 510(k) Summary (21 CFR § 807.92(c))

I: SUBMITTER INFORMATION

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
DomecusConsulting@comcast.net
(650) 343-4813

Date Summary Prepared: July 11, 2017

II: SUBJECT DEVICE INFORMATION

Device Trade Name: Intuitive Surgical® *da Vinci*® Surgical Systems (Models: IS3000, IS4000, IS4200)

Common Name: Endoscopic Instrument Control System

Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR §876.1500)

Regulatory Class: II

Product Code: NAY

III: PREDICATE DEVICE INFORMATION

Predicate Devices: *da Vinci* Surgical Systems (K090993, K131861, K171294)

IV: DEVICE DESCRIPTION

The *da Vinci* Surgical Systems (Models IS3000, IS4000 and IS4200) are software-controlled, electro-mechanical systems designed for surgeons to perform minimally invasive surgery. The *da Vinci* Surgical Systems consist of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and are used with an Endoscope, *EndoWrist* Instruments, and Accessories.

V: INDICATIONS FOR USE

Model IS3000:

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System Model IS3000) 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, 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.

Models IS4000 and IS4200:

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System Models: IS4000 and IS4200) 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.

VI: MODIFICATIONS OF SUBJECT DEVICE

No modifications are being made to the technological characteristics of the subject devices or the cleared indications for use. This 510(k) is being submitted for a labeling change to the Instructions for Use only. Specifically, the subject modification is for a change to the endoscopic contraindication statement in the “General Warnings and Cautions” section in the User Manuals. The original and modified language are noted below:

Original:

Any and all relative and absolute contraindications to endoscopic surgical technique applicable to the use of conventional endoscopic surgical instruments apply to the use of the *da Vinci*¹ System. General, non-procedure specific, contraindications to endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy.

Modified:

Any and all relative and absolute contraindications to endoscopic, thoracoscopic, laparoscopic, and transoral otolaryngology surgical techniques applicable to the use of conventional endoscopic surgical instruments apply to the use of the *da Vinci* System. The device is not intended for use when endoscopic techniques are contraindicated.

VII: DESIGN CONTROL ACTIVITIES

The proposed change to the contraindication statement does not change device usage or the patient population in which the devices are used. The same general contraindications regarding endoscopic surgery are still applicable and are clearly stated in the revised statement. As such, the proposed change does not change the risk profile of the devices. The proposed statement adequately instructs the user to

¹ The “S”, “Xi” or “X” System is specified in each of the pertinent PIFUs.

refrain from device usage when endoscopic surgical techniques are contraindicated.

VIII: CONCLUSION

The labeling modification has no impact on the safety or effectiveness of the *da Vinci* Surgical Systems. As such, the modified devices are substantially equivalent to the predicate devices.