July 26, 2019

Intuitive Surgical, Inc.
Vishal Kanani
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K191736
Trade/Device Name: da Vinci X/Xi 8mm Endoscope Plus, 0 degree, da Vinci X/Xi 8mm Endoscope Plus, 30 degree
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: June 24, 2019
Received: June 28, 2019

Dear Vishal Kanani:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen

Digitally signed by Long H. Chen

Date: 2019.07.26 07:31:56 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name

da Vinci Xi/X Endoscope Plus, 0 degree,
da Vinci Xi/X Endoscope Plus, 30 degree

Indications for Use (Describe)
da Vinci Xi system (Model IS4000)
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.

da Vinci X system (Model IS4200)
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci X 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 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)

- [x] 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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5 510(k) Summary

[As Required by 21 CFR 807.92(c)]

June 24, 2019

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

Official Contact: Vishal Kanani
Sr. Regulatory Affairs Specialist
Ph: 408-523-2035
Fax: 408-523-8907

Trade Name: da Vinci Xi/X Endoscope Plus, 0° (PN 470056);
da Vinci Xi/X Endoscope Plus, 30° (PN 470057)

Common Name: Endoscopic instrument control system, endoscopic instruments and accessories

Classification name: Endoscope and accessories

Regulation: 21 CFR 876.1500

Product Code: NAY and GCJ

Predicate Device: da Vinci Xi/X 8mm Endoscope, 0° (K171426);
da Vinci Xi/X 8mm Endoscope, 30° (K171426)

Device Description:
Similar to the predicate device, the subject IS4000/IS4200 Endoscope Plus is a reusable, sterilizable unit that includes two cameras (left and right eyes) and an integrated cable to connect the endoscope to the Endoscope Controller. The two cameras generate the stereo image of the surgical site. Both the subject and the predicate device endoscopes include light fibers that transmit light from the light source in the Endoscope Controller into the surgical field. Similar to the predicate device, the subject endoscope, can be used laparoscopically (hand-held) at the start of a surgery and then be installed on any Patient Cart Arm. Both the subject and the predicate endoscopes are available in two configurations, 0° and 30° tip angle. However, the subject device has a few design modifications as compared to the predicate...
device. Some of the design modifications include new image sensor, modified optical assembly, new PCA board, modified thermal management design, and modified cable design.

**Intended Use:**
The subject IS4000/IS4200 Endoscope Plus is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging.

**Indications for Use:**
*da Vinci Xi system (Model IS4000)*
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.

*da Vinci X system (Model IS4200)*
The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci X 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 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:**
The subject IS4000/IS4200 Endoscope Plus is equivalent to its predicate, IS4000/IS4200 8mm Endoscope in terms of its indications for use, intended use, design, technology, and performance specifications. The subject device has a few design modifications as compared to the predicate device such as new image sensor, modified optical assembly, new PCA board, modified thermal management design, and modified cable design.

**Performance Data:**
Design Verification and Validation were performed on the subject IS4000/IS4200 Endoscope Plus to demonstrate that the design outputs meet the design inputs and the device performs as intended.

**Design Verification:** The subject device was subjected to a series of bench tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. Testing was performed with a compatible da Vinci surgical system. The design verification testing included confirmation that the device meets the physical, mechanical, electrical, user interface and software specifications.

**Design Validation:**
The design validation testing summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject device. Testing with an animal model was performed to confirm that the subject device functions in accordance with its intended use.

**Electrical Safety and EMC Compatibility:**
Electrical safety and EMC Compatibility testing were performed on the subject device to confirm that the proposed design modifications do not raise new questions of safety and effectiveness.

**Summary:**
Based on the intended use, technical characteristics, and performance data, the subject IS4000/IS4200 Endoscope Plus is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.