DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 13, 2017

Intuitive Surgical, Inc.
Ms. Brittany Cunningham
Sr. Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, CA 94086

Re: K171426
Trade/Device Name: da Vinci Xi 8mm Endoscope, 0 degree, da Vinci Xi 8mm Endoscope, 30 degree
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: May 12, 2017
Received: May 15, 2017

Dear Ms. Cunningham:

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 -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

## 510(k) Summary

| | |
|---|---|
| **510(k) Owner:** | Intuitive Surgical, Inc.<br>1266 Kifer Road<br>Sunnyvale, CA 94086 |
| **Contact:** | Brittany Cunningham, M.S., R.A.C.<br>Sr. Regulatory Affairs Engineer<br>Phone Number: 408-523-0602<br>Fax Number: 408-523-8907<br>Email: BrittanyAnn.Cunningham@intusurg.com |
| **Date Summary Prepared**: | May 12, 2017 |
| **Trade Names:** | *da Vinci Xi* 8 mm Endoscope, 0°<br>*da Vinci Xi* 8 mm Endoscope, 30° |
| **Common Name:** | Endoscopic instruments and accessories |
| **Classification:** | Class II<br>21 CFR 876.1500, Endoscope and Accessories |
| **Product Codes:** | NAY, GCJ |
| **Classification Advisory Committee:** | General and Plastic Surgery |
| **Predicate Devices:** | Main Predicate: K131861 – *da Vinci* Surgical System, Model IS4000<br>Reference Predicate: K141077 – *da Vinci* Firefly Imaging System |

### Device Description

The *da Vinci Xi* 8 mm Endoscope was originally cleared under K131861 on March 28, 2014, for use with the *da Vinci*® Surgical System, Model IS4000. Additional features and indications were cleared under K141077 on August 12, 2014, to add the *da Vinci*® Firefly™ Imaging System. The Intuitive Surgical *da Vinci*® Firefly™ Imaging System uses the endoscope submitted in the original 510(k) K131861 for high definition (HD) visible light imaging and near-infrared fluorescence imaging during minimally invasive surgery.

**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 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.

**Intended Use:**

*da Vinci*® *Xi* Surgical System, Model IS4000, *EndoWrist*® Instruments, and Accessories

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 forth in the Professional Instructions for Use.

*da Vinci*® *Firefly*™ Imaging System

The *da Vinci*® *Firefly*™ Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci Firefly* Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue

perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the *da Vinci Firefly* Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

**Technological Characteristics:**

In terms of intended use, indications for use, and technological characteristics the *da Vinci Xi* 8 mm Endoscope is substantially equivalent to the currently marketed *da Vinci Xi* 8 mm Endoscope, cleared originally under K131861, with additional features and indications cleared under the *da Vinci* Firefly Imaging System (K141077). The minor updates to the optical assembly and the geometry of the distal tip do not substantively change the function of the subject device relative to the function of the predicate device.

**Performance Data:**

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

Design Verification:

The bench testing summarized in this submission verifies the mechanical and labeling requirements for the subject device, including:

- optical;
- illumination;
- mechanical;
- temperature;
- electrical;
- hardware/software compatibility;
- functional;
- reliability/life;
- labeling.

Design Validation:

Validation Testing was performed to confirm that the subject device met the image characteristic requirements, endoscope mechanics requirements, intended use, and user needs of the subject device. Design Validation Testing was performed to confirm that the design modifications to the predicate device do not raise new questions of safety and effectiveness.

**Summary:**

Based on the intended use, indications for use, technological characteristics, and performance data, the modified device (subject), the *da Vinci Xi* 8 mm Endoscope is substantially equivalent to the currently marketed device *da Vinci Xi* 8 mm Endoscope (predicate), cleared under K131861, with additional features and indications cleared under K141077.

# 6.0 INDICATIONS FOR USE STATEMENT

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)*
K171426

Device Name
da Vinci Xi 8 mm Endoscope, 0 degree
da Vinci Xi 8mm Endoscope, 30 degree

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 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
*PRAStaff@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."*