September 21, 2017

Intuitive Surgical, Inc.
Kunal Gunjal
Regulatory Affairs Specialist
1266 Kifer Road,
Building 101
Sunnyvale, California 94086

Re: K170641
Trade/Device Name: Da Vinci S/Si Endoscopes, Da Vinci Xi Endoscopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ, OWN, IZI
Dated: August 24, 2017
Received: August 25, 2017

Dear Kunal Gunjal:

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 (DICE) 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 (DICE) 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

**Indications for Use (Describe)**

The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, and for benign base of tongue resection procedures, general thorascopic surgical procedures, and thoracoscopically assisted cardiomyotomy 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 (except for transoral otolaryngology surgical procedures). 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)

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*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.*
### Indications for Use

**Device Name**  
da Vinci Endoscopes, 8.5mm and 12mm (Fluorescence Imaging Vision System)

**Indications for Use (Describe)**  
The da Vinci Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Fluorescence Imaging Vision 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 and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the da Vinci Fluorescence Imaging Vision 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.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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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 thorascopic surgical procedures and thorascopically-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)
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Indications for Use

510(k) Number (if known)
K170641

Device Name
da Vinci Endoscopes used with the da Vinci Firefly Imaging system

Indications for Use (Describe)

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.

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

☑ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary (K170641)

This 510(k) applies to multiple endoscopes that have been cleared through a number of previous 510(k) Premarket Notifications. It concerns the Reprocessing Instructions provided to users for reprocessing of endoscopes intended for multiple usage. For ease of review, the subject devices have been listed in Tables 1.1 through 1.3 (which are structured based on the device and the da Vinci Surgical System with which it is used). No changes have been made in the design or materials of the subject devices.

Table 1.1: Endoscopes Used with the da Vinci S/Si (IS2000/IS3000) System

| 510(k) Owner | Intuitive Surgical, Inc.  
1266 Kifer Road  
Sunnyvale, CA 94086 |
|--------------|-------------------------------|
| Contact      | Kunal Gunjal  
Regulatory Affairs Specialist, Regulatory Affairs  
Phone Number: 408-523-8017  
Fax Number: 408-523-8907  
Email: Kunal.Gunjal@intusurg.com |
| Date Summary Prepared | September 20, 2017 |

| Trade Name | da Vinci S (IS2000)  
12mm Endoscopes  
da Vinci S (IS2000)  
8.5 mm Endoscopes  
da Vinci Si Endoscopes (8.5mm and 12mm) |
| Common Name | Endoscope and accessories  
Endoscope and accessories  
Endoscope and accessories |
| Classification | Class II,  
21 CFR 876.1500  
Class II,  
21 CFR 876.1500  
Class II,  
21 CFR 876.1500 |
| Classification Advisory Committee: | General and Plastic Surgery  
General and Plastic Surgery  
General and Plastic Surgery |
| Product Codes for Subject Devices (K170641) | NAY  
NAY, GCJ  
NAY |
| Product Codes for Predicate Devices | NAY  
NAY, GCJ  
NAY |
| Predicate Devices | K050369 (use with IS2000 Surgical System), K090993 (TORS indication) and K123329 (updated TORS indication)  
K080155 (use with IS2000 system), K090993 (TORS indication) and K123329 (updated TORS indication)  
K081137 (use with IS3000 system), K090993 (TORS indication) and K123329 (updated TORS indication) |
Table 1.2: Endoscopes Used with the da Vinci Fluorescence Imaging Vision System

| **510(k) Owner** | Intuitive Surgical, Inc.  
| 1266 Kifer Road  
| Sunnyvale, CA 94086 |
| **Contact** | Kunal Gunjal  
| Regulatory Affairs Specialist, Regulatory Affairs  
| Phone Number: 408-523-8017  
| Fax Number: 408-523-8907  
| Email: Kunal.Gunjal@intusurg.com |
| **Date Summary Prepared** | September 20, 2017 |
| **Trade Name** | *da Vinci* Endoscopes, 12mm (Fluorescence Imaging Vision System)  
| *da Vinci* Endoscopes, 8.5 mm (Fluorescence Imaging Vision System) |
| **Common Name** | Endoscopic Instrument Control System  
| Endoscopic Instrument Control System |
| **Classification** | Class II, 21 CFR 876.1500  
| Class II, 21 CFR 876.1500 |
| **Classification Advisory Committee:** | General and Plastic Surgery  
| General and Plastic Surgery |
| **Product Codes for Subject Devices (K170641)** | OWN, IZI, NAY and GCJ  
| OWN |
| **Product Codes for Predicate Devices** | OWN, IZI, NAY and GCJ  
| OWN |
| **Predicate Devices** | K101077 (for use with the *da Vinci* Fluorescence Imaging Vision System) with additional indications cleared under K124031 (expanded indications to include visual assessment of extra-hepatic bile ducts)  
| K124031 (for use with the *da Vinci* Fluorescence Imaging Vision System) |
Table 1.3: Reusable Endoscopes Used with the *da Vinci Xi* (IS4000) System and *da Vinci Firefly Imaging System*

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

**Contact**

Kunal Gunjal  
Regulatory Affairs Specialist, Regulatory Affairs  
Phone Number: 408-523-8017  
Fax Number: 408-523-8907  
Email: Kunal.Gunjal@intusurg.com

**Date Summary Prepared**

September 20, 2017

**Trade Name**

*da Vinci Xi* Endoscopes

**Common Name**

Endoscope and accessories

**Classification**

Class II, 21 CFR 876.1500

**Classification Advisory Committee:**

General and Plastic Surgery

**Product Codes for Subject Devices (K170641)**

NAY, GCJ and IZI

**Product Codes for Predicate Devices**

NAY, GCJ and IZI

**Predicate Devices**

K131861 (Clearance of *da Vinci* Endoscopes for use with the IS4000 system)  
K141077 (Clearance of *da Vinci* Endoscopes for use with the *da Vinci Firefly Imaging System*)

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**Device Description**

The *da Vinci* IS2000 (S), IS3000 (Si), and IS4000 (Xi) Surgical Systems are used in conjunction with reusable *da Vinci* Endoscopes to achieve their intended use. This 510(k) is submitted for changes to Reprocessing Instructions for all reusable *da Vinci* Endoscopes. **Tables 1.4 to 1.6** list the device descriptions for the subject devices impacted by the changes to the reprocessing instructions.

**Table 1.4: Endoscopes Used with the *da Vinci S/Si* (IS2000/IS3000) System**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th><em>da Vinci S/Si</em> Endoscopes (8.5mm and 12mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Description</strong></td>
<td>The IS2000/IS3000 Endoscopes are used to provide an image of the surgical field to the surgeon side console and assistant monitors on the IS2000/IS3000 system. There are two diameters of the endoscopes (12mm or 8.5mm) with either a straight (0°) or angled (30°) tip.</td>
</tr>
</tbody>
</table>
Table 1.5: Reusable Endoscopes Used with the *da Vinci* Fluorescence Imaging Vision System

<table>
<thead>
<tr>
<th>Trade Name</th>
<th><em>da Vinci</em> Endoscopes, 8.5mm/12mm (Fluorescence Imaging Vision System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Description</td>
<td><em>da Vinci</em> Endoscopes, 8.5mm/12mm are a part of the <em>da Vinci</em> Fluorescence Imaging Vision System which is an imaging system for high definition (HD) visible light and near-Infrared fluorescence Imaging during minimally invasive surgery. There are two diameters for the endoscopes (12mm or 8.5mm) with either a straight (0°) or angled (30°) tip.</td>
</tr>
</tbody>
</table>

Table 1.6: Reusable Endoscopes Used with the *da Vinci Xi* (IS4000) System

<table>
<thead>
<tr>
<th>Trade Name</th>
<th><em>da Vinci Xi</em> Endoscopes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Description</td>
<td>The IS4000 Endoscope (8mm) is used to provide an image of the surgical field to the surgeon side console and assistant monitors on the IS4000 System. The IS4000 8 mm endoscope is available with either a straight (0°) or angled (30°) tip.</td>
</tr>
</tbody>
</table>

**Indications for Use:**

Tables 1.7 to 1.9 list the Indications for Use for the devices impacted by the changes to the reprocessing instructions. There is no change in the Indications for Use between the subject and predicate devices.

Table 1.7: Endoscopes Used with the *da Vinci S/Si* (IS2000/IS3000) System

<table>
<thead>
<tr>
<th>Trade Name</th>
<th><em>da Vinci S/Si</em> Endoscopes (8.5mm and 12mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiomyotomy 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 (except for transoral otolaryngology surgical procedures). 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.</td>
</tr>
</tbody>
</table>
Table 1.8: Endoscopes Used with the da Vinci Fluorescence Imaging Vision System

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>da Vinci Endoscopes, 8.5mm/12mm (Fluorescence Imaging Vision System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The da Vinci Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Fluorescence Imaging Vision 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 and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the da Vinci Fluorescence Imaging Vision 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.</td>
</tr>
</tbody>
</table>

Table 1.9: Reusable Endoscopes Used with the da Vinci Xi (IS4000) system and da Vinci Firefly Imaging System

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>da Vinci Xi Endoscopes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>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 thoracic 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.</td>
</tr>
</tbody>
</table>

| da Vinci Endoscopes Used with the 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:
The technological characteristics of the subject devices are identical to the predicate devices.

Performance Data:
Performance test data demonstrates 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 cleaning validations, Human Factors validation studies, Chemical Disinfection Efficacy and Compatibility validation studies. Design validation and biocompatibility testing were not repeated as the subject device design, materials, and manufacturing processes are identical to the predicate devices.

Cleaning Validation
The cleaning validation testing summarized in this submission validates the efficacy of the cleaning process in the Reprocessing Instructions in accordance with the following standards and guidance documents:

- AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR 30: 2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Cleaning validation testing was performed using devices within the product family that represent the greatest challenge for the cleaning process. The Cleaning Efficacy test evaluated the cleaning process (as described in the Reprocessing Instructions) for the devices using qualitative visual inspection and quantitative endpoints.

Chemical Disinfection Efficacy Validation
The disinfection validation testing summarized in this submission validates the efficacy of the chemical disinfection process in the Reprocessing Instructions in accordance with the following guidance documents:


Efficacy of the chemical disinfection process (as described in the Reprocessing Instructions) was performed using devices that represent significant challenges to the disinfection step within the scope of the intended use. The chemical disinfection efficacy testing evaluated the efficacy of the
disinfection process in the Reprocessing Instructions using a quantitative endpoint i.e. 6-log10 reduction of typical vegetative organisms, such as Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives of the Klebsiella-Enterobacter group.

**Chemical Disinfection Compatibility Validation**

The chemical disinfection compatibility validation testing summarized in this submission validates the compatibility of the da Vinci Endoscopes with the chemical disinfection process. Devices were subjected to multiple chemical disinfection cycles and visually inspected for material changes and degradation.

**Human Factors Testing**

The Reprocessing Instructions underwent a rigorous Human Factors testing process. This process included:

- **Preliminary Evaluation**: A preliminary evaluation was completed to better understand the users, uses, and use environment.

- **Usability Risk Analysis (URA)**: Task and Use Error analysis was conducted for Reprocessing. This analysis included the process and Reprocessing Instructions.

- **Design Team Participation**: Human Factors Engineers participated in design meetings and played a significant role in the visual design and content development.

- **Formative Testing**: Formative tests were completed during the development of the new Reprocessing Instructions.

- **Validation Testing**: Validation test of representative Reprocessing Instructions was completed with representative end users.

This validation study assessed the usability, effectiveness, and use safety of the Reprocessing Instructions.

**Summary:**

Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject device is substantially equivalent and is as safe, as effective, and performs as well as the legally marketed predicate devices listed in **Tables 1.1 to 1.3**.