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

September 21, 2016

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

Re: K162411
Trade/Device Name: Da Vinci Xi 12-8 mm Reducer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 26, 2016
Received: August 29, 2016

Dear Mr. 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. 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 Part 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 Parts 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,

Christopher J. Ronk -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

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)*
K162411

Device Name
da Vinci Xi 12 - 8 mm Reducer

Indications for Use *(Describe)*
The Intuitive Surgical EndoWrist® Stapler 45, Stapler 45 Reloads and other Stapler Accessories are intended to be used with the da Vinci® Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

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: Vishal Kanani
Sr. Regulatory Affairs Specialist
Phone Number: 408-523-2035
Fax Number: 408-523-8907
Email: vishal.kanani@intusurg.com

Date Summary Prepared: August 26, 2016

Trade Name: *da Vinci Xi* 12 – 8 mm Reducer

Common Name: Endoscope and accessories

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Codes: NAY

Classification Advisory Committee: General and Plastic Surgery

Predicate Device: K140553 – EndoWrist® Stapler 45 and Stapler 45 Reloads

Device Description

The *da Vinci Xi* 12 – 8 mm Reducer is a sterile, single use hollow cylinder with an integrated seal that is inserted into the *da Vinci Xi* 12 mm & Stapler Cannula/Cannula Seal assembly to support the use of *da Vinci Xi* 8 mm instruments and endoscopes.

The Reducer consists of three components – a tube, handle, and an integrated seal to allow a *da Vinci Xi* 8 mm instrument or endoscope to be used with a 12 mm & Stapler Cannula while maintaining pneumoperitoneum. The latch on the Reducer snaps onto the *da Vinci Xi* Stapler Cannula Seal by a molded-in latch flexure on the device.

Intended Use/Indications for Use:

The Intuitive Surgical EndoWrist® Stapler 45, Stapler 45 Reloads and other Stapler Accessories are intended to be used with the *da Vinci*® Surgical System (Model 1S4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

Technological Characteristics:

The modification to the design of the current 12 – 8 mm Reducer is the addition of a 303 Stainless Steel ring at the distal end of the device. This change does not impact the intended use and the fundamental scientific technology of the device. The modified device (subject) and the current device (predicate) share similar technological characteristics.

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 dimensional, mechanical, and labeling requirements of the subject device. Insertion force, retraction force, insertion friction, latch disengagement force, insertion axis range of motion, and internal seal leak rate were some of the requirements that were tested in addition to adequacy of labeling required to communicate compatibility of the subject device.

Design Validation:
The testing summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject device. Tests with an animal model were performed to confirm that the subject device functions in accordance with its intended use. The subject devices' compatibility with the cannulas, cannula seals, and size-compatible endoscopes and instruments was tested to ensure they maintain insufflation when used together.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the modified device (subject), 12 – 8 mm Reducer is substantially equivalent to the current device in the market (predicate).