DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 4, 2016

Intuitive Surgical, Inc.
Mr. Manish Patel
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, CA 94086

Re: K152421
Trade/Device Name: IS4000 EndoWrist Stapler 30 and Stapler 30 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: February 1, 2016
Received: February 2, 2016

Dear Mr. Patel:

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 -A

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

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)*
To be assigned K152421

Device Name
IS4000 EndoWrist® Stapler 30 and Stapler 30 Reloads

Indications for Use *(Describe)*
The Intuitive Surgical EndoWrist® Stapler 30 Instrument and Stapler 30 Reloads 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 is indicated for adult and pediatric use. The device can be used with staple line or tissue buttressing material.

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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

7 510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Manish Patel Sr. Regulatory Affairs Specialist Phone Number: 408-523-2185 Fax Number: 408-523-8907 Email: manish.patel@intusurg.com
Date Summary Prepared:	August 24, 2015
Trade Name:	IS4000 *EndoWrist*® Stapler 30 and Stapler 30 Reloads
Common Name:	Endoscope and accessories; Surgical Stapler and implantable staples
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories 21 CRF 878.4750, Implantable Staple
Product Codes:	NAY (Endoscope and accessories) GDW (Implantable Staple)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	1. IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads – K140553 (primary) 2. ENDOPATH Endocutter with Gray Cartridge – K033269 (secondary)

Device Description:

The Intuitive Surgical IS4000 *EndoWrist*® Stapler 30 and Stapler 30 Reloads is a reusable surgical stapler system designed for use exclusively with the Intuitive *da Vinci* Surgical System (Model IS4000). It is intended for resection, transection and/or creation of anastomoses in surgery. The instrument achieves its intended use by placing multiple staggered rows of implantable staples in the target tissues (stapling) followed by cutting of the target tissue along the middle of the staple line (transection). The Stapler 30 Instrument is a reusable, fully wristed articulating device offered in two configurations, a straight tip and a curved-tip. The Stapler 30 Reloads consist of a single-

use cartridge that contains multiple, staggered rows of implantable staples, and a stainless steel knife. The reloads are available in four configurations (Gray, White, Blue and Green) to accommodate tissues of various thicknesses (e.g., lung, stomach, and bowel).

Intended Use:

The IS4000 *EndoWrist*® Stapler 30 and Stapler 30 Reloads are intended to resect, transect and/or create anastomoses in surgery.

Indications for Use:

The Intuitive Surgical *EndoWrist*® Stapler 30 Instrument and Stapler 30 Reloads 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 is indicated for adult and pediatric use. The device can be used with staple line or tissue buttressing material.

Technological Characteristics:

The subject devices, IS4000 *EndoWrist*® Stapler 30 and Stapler 30 Reloads, are technologically very similar to the primary predicate devices, IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads (cleared under K140553). They have the same architecture design as the predicate except for differences like shorter staple line length (30 mm on the subject device vs. 45 mm on the predicate), addition of the curved-tip configuration for the instrument, and use of a Gray color reload with shorter formed staple height.

Performance Data:

Performance data (bench and animal testing) demonstrate that the subject devices are substantially equivalent to the predicate devices and that the design output meets the design input requirements. The testing included dimensional measurements, mechanical and functional verification, simulated use in animal models, and human factors assessment.

Bench Testing:

The subject devices, Stapler 30 Instrument and Stapler 30 Reloads, were subjected to a series of bench tests to evaluate the performance and to demonstrate that the design outputs meet the input requirements. The design verification testing included:

- Physical Specifications
- Mechanical Requirements
- Electrical Requirements
- User Interface Requirements
- Equipment Interface Requirements

Animal Validations:

A series of tests were performed using simulated clinical models (animal) to evaluate the performance of the subject devices, IS4000 *EndoWrist*® Stapler 30 and Stapler 30 Reloads. This included Animal Survival Studies, Staple Line Performance and Formation, Buttress Material Compatibility Testing, Design Validation Testing, Burst Pressure Testing, and SmartClamp™ evaluation. A side-by-side comparison between the subject and predicate devices (IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads and the ENDOPATH Endocutter with Gray Cartridge was performed in the Animal Survival Studies, Staple Line Performance and Formation, and Burst Pressure Testing to demonstrate substantial equivalence between the subject and predicate devices. Buttress Material Compatibility Testing, SmartClamp evaluation, and Design Validation Testing demonstrated that the design outputs of the subject device fulfill the design input requirements and that user needs and intended uses are met.

Human Factors Evaluation:

As part of the Usability Engineering Process for the Stapler 30 and Stapler 30 Reloads, the Usability Risk Analysis was updated to identify any new usability characteristics related to safety, as well as foreseeable hazards and hazardous situations. All risks were assessed as having "Tolerable" or "Broadly Acceptable" pre-mitigated risk profiles. As a result, no further usability testing was conducted to evaluate the safety and usability of the subject devices.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject devices, IS4000 *EndoWrist*® Stapler 30 and Stapler 30 Reloads are substantially equivalent to the predicate devices, the IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads and the ENDOPATH Endocutter with Gray Cartridge.