DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2017

Intuitive Surgical, Inc.
Ms. Cheryl Wu
Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K170508
Trade/Device Name: Endowrist Stapler 45 Instrument, Endowrist Stapler 45 Reloads, Endowrist Stapler 30 Instrument, Endowrist Stapler 30 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: February 17, 2017
Received: February 21, 2017

Dear Ms. Wu:

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" (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,

Jennifer R. Stevenson -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)*
K170508

Device Name
EndoWrist Stapler 45 and Stapler 45 Reloads
EndoWrist Stapler 30 and Stapler 30 Reloads

Indications for Use *(Describe)*

EndoWrist Stapler 45 and Stapler 45 Reloads
The Intuitive Surgical EndoWrist Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with a compatible da Vinci Surgical System 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).

EndoWrist Stapler 30 and Stapler 30 Reloads
The Intuitive Surgical EndoWrist Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with a compatible da Vinci Surgical System 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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510(k) Summary

510(k) Submitter:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Cheryl Wu Regulatory Affairs Engineer Phone: 408-523-6401 Fax: 408-523-1390 Email: cheryl.wu@intusurg.com
Date Summary Prepared:	February 17, 2016
Trade Name:	*EndoWrist* Stapler 45 and Stapler 45 Reloads *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 CFR 878.4750, Implantable Staple
Product Codes:	NAY GDW
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	K140553 – *EndoWrist* Stapler 45 and Stapler 45 Reloads K152421 – *Endowrist* Stapler 30 Instrument and Stapler 30 Reloads

Intended Use (*EndoWrist* Stapler 45 and Stapler 45 Reloads):

To resect, transect and/or create anastomoses in surgery.

Indications for Use (*EndoWrist* Stapler 45 and Stapler 45 Reloads):

The *Intuitive Surgical EndoWrist* Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with a compatible *da Vinci* Surgical System 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).

Device Description (*EndoWrist* Stapler 45 and Stapler 45 Reloads):

The Intuitive Surgical *EndoWrist* Stapler 45, Stapler 45 Reloads, and Accessories are components of a reusable surgical stapler system designed for use with a compatible *da Vinci* Surgical System. This stapler system is intended for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery 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 implantable staples, trade name Stapler 45 Reloads, are provided in a separate single use cartridge and are available in the following three configurations to accommodate tissues of various thickness:

- 2.5 mm staple size single use reload (White Reload)
- 3.5 mm staple size single use reload (Blue Reload)
- 4.3 mm staple size single use reload (Green Reload)

Accessories, including cannulae, obturators, a cannula seal, and a cannula reducer, are provided to support the interface of the *EndoWrist*® Stapler 45 with a compatible *da Vinci* Surgical System.

Intended Use (*EndoWrist* Stapler 30 and Stapler 30 Reloads):

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

Indications for Use (*EndoWrist* Stapler 30 and Stapler 30 Reloads):

The *Intuitive Surgical EndoWrist* Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with a compatible *da Vinci* Surgical System 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.

Device Description (*EndoWrist* Stapler 30 and Stapler 30 Reloads):

The Intuitive Surgical *EndoWrist* Stapler 30 and Stapler 30 Reloads are components of a reusable surgical stapler system designed for use with a compatible *da Vinci* Surgical System. This stapler system 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 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).

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Indications for Use:

Technological Characteristics:

The *EndoWrist* Stapler 45 and Stapler 45 Reloads (hereinafter referred to as "Stapler 45 System") and *EndoWrist* Stapler 30 and Stapler 30 Reloads (hereinafter referred to as "Stapler 30 System") are identical to their predicate devices in terms of design, technology, and performance specifications.

The purpose of this submission is to change the Indications for Use for both the Stapler 45 and Stapler 30 Systems' Indications for Use statements. Specific references to compatible systems (i.e. "Xi", "Model IS4000") have been removed from both the Stapler 45 and Stapler 30 Systems' Indications for Use statements. The reference to "compatible *da Vinci* Surgical Systems" in the subject Indications for Use coupled with identification of specific systems in the Compatibility Information section of the User Manual for the subject devices is essentially equivalent to the reference to "Model IS4000" in the predicate Indications for Use statements.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of labeling modifications on the predicate devices**.** Design verification and design validation testing were not required since design inputs were not changed.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject devices *EndoWrist* Stapler 30 and 45 Systems are substantially equivalent to currently marketed predicate devices.