DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 31, 2017

Intuitive Surgical, Inc.
Ms. Doreen Nakamura
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K171388
Trade/Device Name: EndoWrist Stapler 45 System and Stapler 45 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: May 10, 2017
Received: May 11, 2017

Dear Ms. Nakamura:

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

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)*
K171388

Device Name
EndoWrist Stapler 45 System and Stapler 45 Reloads

Indications for Use *(Describe)*
The Intuitive Surgical EndoWrist Stapler 45 System and Stapler 45 Reloads are intended to be used with the da Vinci Si Surgical System (Model IS3000) for resection, transection and/or creation of anastomoses in General, Gynecologic, and Urologic surgery. The device can be used with staple line and 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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K171388

510(k) Summary

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

Contact: Doreen Nakamura, R.A.C.
Sr. Regulatory Affairs Specialist
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Date Summary Prepared: May 16, 2017

Trade Names: *EndoWrist*® Stapler 45 System and Stapler 45 Reloads

Common Name: Endoscopic instruments and accessories

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 Devices: K113706– *EndoWrist* Stapler 45 System and Stapler 45 Reloads

Device Description

The Intuitive Surgical *EndoWrist*® Stapler 45, Stapler 45 Reloads and Accessories is a reusable surgical stapler system designed for use exclusively with the Intuitive *da Vinci* Surgical System (Model IS3000). It is intended for resection, transection and/or creation of anastomoses in General, Gynecologic, and Urologic surgery by placing multiple 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 two configurations to accommodate tissues of various thickness:

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

Accessories, including cannula, obturator, cannula reducer, and a cannula seal, are provided to support the interface of the *EndoWrist*® Stapler 45 with the *da Vinci* Surgical System (Model IS3000).

Intended Use:

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

Indications for Use:

The *EndoWrist* Stapler 45 System and *EndoWrist* Stapler 45 Reloads are intended to be used with the *da Vinci Si* Surgical System (Model IS3000) for resection, transection and/or creation of anastomoses in General, 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 predicate Stapler 45 Instrument is a change in materials to 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.

Comparison:

The predicate device used for the determination of substantial equivalence is the previously cleared *EndoWrist* Stapler 45 System and Stapler 45 Reloads (K113706). See comparison in **Table 1**.

Table 1: Device Comparison

Item	**Subject Device** *EndoWrist* Stapler 45 System and Stapler 45 Reloads	**Predicate Device** *EndoWrist* Stapler 45 System and Stapler 45 Reloads (K113706)
Devices, Trade Name	EndoWrist® Stapler 45 System and Stapler 45 Reloads	IDENTICAL
Product Code	NAY	IDENTICAL
Regulation Number and Name	21 CFR 876.1500, Endoscope and Accessories	IDENTICAL
Classification Advisory Committee	General and Plastic Surgery	IDENTICAL
Classification	II	IDENTICAL
Intended Use	To resect, transect and/or create anastomoses in surgery.	IDENTICAL
Indications for Use	The *EndoWrist* Stapler 45 System and *EndoWrist* Stapler 45 Reloads are intended to be used with the *da Vinci Si* Surgical System (Model IS3000) for resection, transection and/or creation of anastomoses in General, Gynecologic and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).	IDENTICAL
Prescription Use	Physician use only	IDENTICAL
Where used (hospital, home ambulance, etc.)	Hospital	IDENTICAL
Mechanism of action	The stapler instrument achieves its intended function by placing multiple staggered rows of implantable staples in the target tissue followed by cutting of the target tissue along the middle of the staple line.	IDENTICAL

Item	**Subject Device** *EndoWrist* Stapler 45 System and Stapler 45 Reloads	**Predicate Device** *EndoWrist* Stapler 45 System and Stapler 45 Reloads (K113706)
Stapler Motor Pack and cable	Stapler Motor Pack 372300 Cable 372032	IDENTICAL
Stapler Reloads Sterilization Method	Blue 41645B Green 41445G EO	IDENTICAL IDENTICAL
Manual Unclamp Tool (EndoWrist Stapler Release Kit)	EndoWrist Stapler Release Kit 381181	IDENTICAL
Stapler Cannula Kit	EndoWrist Stapler Cannula Kit 420378	IDENTICAL
Stapler Sheath	Stapler Sheath 410370	IDENTICAL
Stapler 45 Instrument Type of Use Sterilization Method	Stapler 45 Instrument 410298 • Reusable • Steam	IDENTICAL
Stapler 45 Instrument Labeling Change	Labeling divided into two documents and added Wall Chart • Stapler Instrument and Accessories Manual • Reprocessing Instructions • Wall Chart (derivative of Reprocessing Instructions)	Stapler Instrument and Accessories Manual containing Reprocessing Instructions, Section 4
Stapler 45 Instrument Cam Change	Stainless steel with better corrosion resistant properties and carbon coating on all surfaces	Stainless steel, no coating
Stapler 45 Instrument Anvil Change	Carbon coating removed from anvil surfaces interfacing with cam	Carbon coating present on all surfaces, except for cosmetic top surface
Stapler 45 Instrument Marking Change	"Autoclave" added to instrument housing .	Not present

Design Verification

Table 2 lists design verification testing performed on both subject and predicate devices and sub- assemblies.

Table 2: Design Verification Performed

Testing	Summary
Design Verification	Appropriate verification testing was performed on the subject device to evaluate design specifications such as physical, mechanical, and any requirements that may be affected by the design change. Distal subject device subassemblies built with the new cam material were subjected to a 3X the maximum calculated load. Subject devices were cleaned and sterilized and then tested for clamp, fire, electrical connectivity of reload and Stapler Motor Pack. **Subject device and subject device sub-assemblies met design verification specifications.**
Design Verification Sub-Assembly	Appropriate verification testing was performed on the subject device sub-assembly to evaluate design specifications such as environmental assisted cracking susceptibility and requirements that have been affected by the design change. **Subject device sub-assemblies met design verification specifications.**
Reliability/Life Testing	Verification testing was performed to evaluate requirements that may be affected by the design change. Subject devices were fired, clamped and reprocessed for the estimated life of the product. **Subject device met reliability/life specifications.**

Design Validation:

Design Validation testing was performed on subject and predicate devices to confirm the subject device meets the user needs and intended use in a clinical setting. The testing summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject device. Tests with an animal model evaluated performance based on comparative tissue approximation, hemostasis, and staple formation in accordance with its intended use. Design Validation results confirm the design modifications to the Stapler 45 Instrument do not raise any new questions of safety and effectiveness.

Summary:

The subject *EndoWrist* Stapler 45 System and Stapler 45 Reloads and the predicate *EndoWrist* Stapler 45 System and Stapler 45 Reloads (K113706) have the same intended use, indications for use, technological characteristics, performance data, and utilize the same disposable accessories and instrument accessories. The results of the design verification and validation tests do not raise new issues of safety and effectiveness.

In conclusion, the *EndoWrist* Stapler 45 System and Stapler 45 Reloads described in this submission is substantially equivalent to the predicate device.