510(k) Summary

JUL 2 5 2014

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Dawn Chang Sr. Regulatory Affairs Specialist Phone Number: 408-523-2347 Fax Number: 408-523-8907 Email: dawn.chang@intusurg.com
Date Summary Prepared:	July 24, 2014
Trade Name:	***EndoWrist***® Stapler 45 and Stapler 45 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:	Intuitive Surgical ***EndoWrist***® Stapler 45 System and Stapler 45 Reloads (for use with *da Vinci*® IS3000 System), and ENDOPATH® ETS Reload (White)

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 IS4000). It 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 the *da Vinci* Surgical System (Model IS4000).

Intended Use:

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

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 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).

Technological Characteristics:

The Intuitive Surgical *EndoWrist* Stapler 45, Stapler 45 Reloads, and other Stapler Accessories (subject devices) are equivalent to the predicate device, *EndoWrist* Stapler 45 System, Stapler 45 Reloads, and Accessories (for use with the *da Vinci* IS3000 System) in terms of technological characteristics and intended use. Modifications to the *EndoWrist* Stapler 45, Stapler 45 Reloads, and Accessories include: (1) an update of the instrument design for compatibility with the *da Vinci* Surgical System (Model IS4000), (2) inclusion of a thoracic surgery indication with the addition of the Stapler 45 White Reload, and (3) a set of modified accessories to support use with the *da Vinci* Surgical System (Model IS4000).

Note that the subject devices, the *EndoWrist* Stapler 45, Stapler 45 Reloads, and other Stapler Accessories are not compatible with the *da Vinci* IS3000 System. Similarly, the predicate devices, *EndoWrist* Stapler 45 System, Stapler 45 Reloads, and Accessories, are not compatible with the *da Vinci* IS4000 System.

Performance Data:

Performance test data (bench, animal, and cadaver tests) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. Bench testing included dimensional measurements, mechanical and functional verification, as well as electrical safety and electromagnetic compatibility assessment per IEC standards. In addition, staple formation, staple line integrity, and transection performance were evaluated in animal cadaver models with various reloads and buttress materials. The following table provides a quick summary:

Testing	IS4000 Stapler	IS3000 Stapler
Animal Survival Studies with side-by-side comparison between subject and predicate devices		
• Small bowel anastomoses (14-day follow-up)	X	X
• Gastrectomy (14-day follow up)	X	X
• Lung Resection (7-day follow up)	X	X
• Pneumonectomy (28-day follow up)	X	*
Staple formation and transection testing	X	X
Buttress material compatibility testing	X	X
Burst pressure testing	X	X

*IS3000 Stapler does not have thoracic (lung) indications

Human Factors and Usability Testing:

Summative usability validation studies were conducted with users (surgeons and operating room staff) for the *EndoWrist* Stapler 45, Stapler 45 Reloads, and Accessories. These studies were conducted in a simulated operating room and involved typical workflow scenarios as well as certain troubleshooting scenarios related to safety-critical tasks. Results of the validation studies and the other elements of the human factors engineering program provide evidence that the *EndoWrist* Stapler 45, Stapler 45 Reloads, and Accessories are safe and effective when used by the intended users in the intended use environment.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the Intuitive Surgical *EndoWrist* Stapler 45, Stapler 45 Reloads, and Accessories are substantially equivalent to the predicate device, the Intuitive Surgical *EndoWrist* Stapler 45 System, Stapler 45 Reloads, and Accessories.

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

July 25, 2014

Intuitive Surgical, Inc.
Ms. Dawn Chang
Senior Regulatory Specialist
1266 Kifer Rd
Sunnyvale, California 94086

Re: K140553
Trade/Device Name: Endowrist stapler 45 and stapler 45 reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories; Surgical Stapler And Implantable Staples
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: June 26, 2014
Received: June 27, 2014

Dear Ms. Chang,

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

David [illegible]use -S

for Binita 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 on last page.

510(k) Number *(if known)*
K140553

Device Name
EndoWrist® Stapler 45, Stapler 45 Reloads, and Accessories

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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