K113706

510(k) Summary

OCT 17 2012

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Crystal Ong Sr. Regulatory Affairs Specialist Ph: 408-523-8636; Fax: 408-523-1390 crystal.ong@intusurg.com
Date Summary Prepared:	August 3, 2012
Trade Name:	*EndoWrist*® Stapler 45 System and Stapler 45 Reloads
Common Name:	Endoscope and accessories Surgical stapler and implantable staples
Classification:	Endoscope and accessories (21 CFR 876.1500, Product Code NAY) Surgical Devices, Implantable Staples (21 CFR 878.4750, Product Code GDW)
Predicate Device:	Ethicon ETS Flex-45 Endoscopic Articulating Linear Cutter (K002398) *EndoWrist*® Instruments (cleared for use with *da Vinci Si* Surgical System, K081137)

Device Description:

The Intuitive Surgical *EndoWrist* Stapler 45 System when used with the compatible Stapler 45 Reloads delivers multiple rows of staples and transects the tissue along the middle of the staple line. The *EndoWrist* Stapler 45 System is a reusable device and the Stapler 45 Reloads (available in various sizes) are single-use/disposable devices.

Intended Use:

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 or tissue buttressing material (natural or synthetic).

Technological Characteristics:

The Intuitive Surgical *EndoWrist* Stapler 45 System and Stapler 45 Reloads are substantially equivalent to the predicate device in terms of technological characteristics and intended use.

Performance Data:

Performance test data (bench and animal tests) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements.

Summary:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Intuitive Surgical, Incorporated
% Ms. Meghna Sridharan
Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

OCT 17 2012

Re: K113706
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
Dated: October 5, 2012
Received: October 9, 2012

Dear Ms. Sridharan:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number if known: K113706

Device Name: *EndoWrist*® Stapler 45 System and Stapler 45 Reloads

INDICATION FOR USE:

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 or tissue buttressing material (natural or synthetic).

Prescription Use X AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113706