K110639

DEC 28 2011

510(k) Summary
[As Required by 21 CFR 807.92(c)]

Date Summary Prepared: March 2, 2011

Submitter: Intuitive Surgical, Inc.
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Trade Name: Intuitive Surgical EndoWrist One Vessel Sealer

Common Name: System, Surgical, Computer Controlled Instrument

Product Code: NAY

Classification: Endoscope and accessories, 21 CFR 876.1500

Predicate Devices: Intuitive Surgical EndoWrist Bipolar Instrument (K012833)
SurgRX, Inc., EnSeal PTC (K071728)

Device Description:

The *EndoWrist One* Vessel Sealer is an electrosurgical sealing and cutting instrument to be used in conjunction with the *da Vinci Si* Surgical System and the ERBE VIO 300 D electrosurgical generator. The outside diameter (O.D.) of the instrument shaft is 8.5 mm and the working length is 38 cm. The instrument is provided sterile and is a single-use, disposable device. The distal end has jaws with bipolar electrodes for sealing vessels and contains a cutting blade that extends through the jaws to transect sealed vessels and other tissues. The sealing and cutting functions are operated by the da Vinci Si Surgical System foot pedals.

The ERBE VIO 300 D generator provides the high frequency (radio frequency) electrical current for tissue sealing.

Intended Use/Indications for Use:

The EndoWrist One Vessel Sealer is a bipolar electrosurgical instrument for use with the da Vinci Si Surgical System and the ERBE VIO 300 D electrosurgical generator. It is intended for bipolar coagulation and mechanical transection of vessels up to 7mm in diameter and tissue bundles that fit in the jaws of the instrument. The EndoWrist One Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Technological Characteristics: The EndoWrist One Vessel Sealer system is substantially equivalent to the predicate devices in terms of its indications for use, design, technology and performance.

Performance Data: Performance tests (bench and animal lab tests) were conducted to demonstrate that the subject device is substantially equivalent to the predicate devices and that the design output meets the design input requirements. The results of the testing did not raise any new issues of safety or effectiveness as compared to the predicate devices.

Summary: Based on the indications for use, design, technological characteristics and performance data, the EndoWrist One Vessel Sealer system is substantially equivalent to the predicate devices in terms of intended use, safety, effectiveness, and performance.

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

DEC 2 8 2011

Intuitive Surgical, Inc.
% Mr. Brandon Hansen
Sr. Regulatory Affairs Manager
1266 Kifer Road
Sunnyvale, California 94086

Re: K110639
Trade/Device Name: EndoWrist One Vessel Sealer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: December 20, 2011
Received: December 23, 2011

Dear Mr. Hansen:

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

510(k) Number if known: K110639

Device Name: EndoWrist One Vessel Sealer

INDICATIONS FOR USE:

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Prescription Use __X__ (Per 21 CFR 801 Subpart D) Subpart C)

AND/OR

Over-the-Counter Use _____ (Per 21 CFR 807

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhorn

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

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