APR - 8 2011

510(k) Summary

(As Required by 21 CFR 807.92(c))

Date: 6/4/2010

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

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Trade Name: *da Vinci* Wireless Connectivity Option

Common Name: Endoscopic Instrument Control System, Endoscopic Instruments, and accessories

Classification: System, Surgical, Computer Controlled Instrument 21 CFR 876.1500)

Predicate Device: K081207: *Intuitive Surgical® da Vinci® S™* Surgical System, Model IS2000, with *da Vinci* Connect™ and *da Vinci* OnSite™

Device Description: The *da Vinci* Wireless Connectivity Option for the *da Vinci S* Surgical System Model IS2000 with *da Vinci* Connect™ and *da Vinci* OnSite, is a minor modification that will provide an alternative to the wired Ethernet connection in the existing device. Specifically, the Wireless Connectivity Option will provide IEEE 802.11 wireless connectivity between the *da Vinci S Surgical System* and the hospital's Internet Protocol (IP) infrastructure.

Intended Use: The *da Vinci* Wireless Connectivity Option is intended to provide a suitable alternative for the wired Ethernet connection between the *da Vinci* Surgical System and the hospital's Internet Protocol (IP) infrastructure.

The *Intuitive Surgical* Endoscopic Instrument Control System (IS2000 *da Vinci S* Surgical System with *da Vinci* Connect™, *da Vinci* OnSite) is intended to assist in the accurate control of *Intuitive Surgical* Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecological laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general cardiovascular and non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system is indicated for adult and pediatric use. The system can also be employed, with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the Professional Instructions for Use.

Technological Characteristics: The subject device is identical in intended use, design and technology as compared to the predicate device.

Performance Data: Performance tests (bench tests) were conducted to demonstrate conformance to Design Controls, and that the design output meets the design input requirements. The results of the testing do not raise any new issues of safety or efficacy.

Summary: Based on the technical characteristics, intended use and performance test data, the *Intuitive Surgical*® *da Vinci*® *S*™ Surgical System, Model IS2000, with *da Vinci* Connect™, *da Vinci* OnSite™ and Wireless Connectivity Option has been determined to be equivalent in safety, efficacy, and performance to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

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Re: K101581
Trade/Device Name: Intuitive Surgical® da Vinci® S™ Surgical System, Model IS2000 with Connect™ OnSite and Wireless Connectivity Option
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: February 10, 2011
Received: February 11, 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,

for

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: K101581

Device Name: *Intuitive Surgical® da Vinci® S™* Surgical System, Model IS2000 with Connect™ OnSite and Wireless Connectivity Option

INDICATION FOR USE:

The *da Vinci* Wireless Connectivity Option is intended to provide a suitable alternative for the wired Ethernet connection between the *da Vinci* Surgical System and the hospital's Internet Protocol (IP) infrastructure.

The *Intuitive Surgical* Endoscopic Instrument Control System (IS2000 *da Vinci S* Surgical System with *da Vinci* Connect™, *da Vinci* OnSite) is intended to assist in the accurate control of *Intuitive Surgical* Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecological laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general cardiovascular and non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system is indicated for adult and pediatric use. The system can also be employed, with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the Professional Instructions for Use.

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 K101581