K123463

6. 510(K) SUMMARY

510(K) SUMMARY
(per 21 CFR 807.92)

DEC 0 3 2012

Submitter: Intuitive Surgical, Inc.
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Contact: Crystal Ong
Sr. Regulatory Affairs Specialist

Date Summary Prepared: **November 7, 2012**

Device Name:

Trade Name:	*Intuitive Surgical*® *da Vinci*® *Si*™ Surgical System SmartPedals™
Common Name:	Endoscopic instrument control system
Classification Name:	Endoscope and Accessories (21 CFR 876.1500, Product Code NAY)

Predicate Device: The *Intuitive Surgical*® *da Vinci*® *Si*™ Surgical System (with Functional Footpedal Mapping) was originally cleared under K081137, with additional indications under K090993 (TORS).

Device Description: The *Intuitive Surgical da Vinci Si* Surgical System is a computer-assisted device designed to facilitate complex surgery using a minimally invasive approach. The system consists of three main components: the Surgeon Console, the Patient Cart, and the Vision Cart. The Surgeon Console houses the hand (Master Tool Manipulators or MTMs) and foot controls for the system. These controls allow the surgeon to manipulate the endoscopic instruments and camera located on the Patient Cart. The Vision Cart houses the system's image processing unit as well as the Instrument Control Box and any electrosurgical generators used in conjunction with the endoscopic instruments.

The proposed modification to the *Intuitive Surgical da Vinci Si* Surgical System user interface will result in a change from Functional Footpedal Mapping to Left/Right Associative Footpedal Mapping. Currently, under Functional Footpedal Mapping, instruments are assigned to

	footpedal banks according to their function (monopolar, bipolar, etc). The proposed change to Left/Right Associative Footpedal Mapping will provide a more intuitive user interface by associating each pedal bank with a hand controller or "master tool manipulator" (MTM). Therefore, instruments assigned to the left MTM will be controlled by the left pedal bank and the instruments assigned to the right MTM will be controlled by the right pedal bank.
Indications For Use:	The *Intuitive Surgical* Endoscopic Instrument Control System 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, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1and T2, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used 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 (*da Vinci Si* System, with Left/Right Associative Footpedal Mapping) is substantially equivalent in technological characteristics in terms of the intended use, indications for use and technological characteristics as compared to the *da Vinci Si* System, with Functional Footpedal Mapping (the predicate device).
Performance Data:	Human Factors testing was conducted to demonstrate that the subject device is substantially equivalent to the predicate device in terms of error rate and risk profile. Software verification testing was performed to confirm that the design specifications meet the design requirements. The results of the testing did not raise any new types of safety or effectiveness questions.
Summary:	Based on the intended use, indications for use, technological characteristics, and performance data, the modified *Intuitive Surgical da Vinci Si* Surgical System, with Left/Right

Associative Footpedal Mapping, is substantially equivalent to the *Intuitive Surgical da Vinci Si* Surgical System, with Functional Footpedal Mapping (the predicate device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Intuitive Surgical, Incorporated
% Ms. Crystal Ong
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

December 3, 2012

Re: K123463
Trade/Device Name: Intuitive Surgical® da Vinci® Si™ Surgical System SmartPedals™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: November 7, 2012
Received: November 9, 2012

Dear Ms. Ong:

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,

Peter D. Rumm -S

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

Enclosure

510(k) Number if known:

Device Name: *Intuitive Surgical® da Vinci® Si™* Surgical System SmartPedals™

INDICATIONS FOR USE:

The *Intuitive Surgical* Endoscopic Instrument Control System 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, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used 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__ (Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use (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)

Dwight Yen
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(Division Sign-off)
Division of Surgical Devices
510(k) Number __K123463__