Section II

510(k) SUMMARY

APR 2 9 2005

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K050369

Date	April 26, 2005
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Mike Yramategui Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 e-mail: mike.yramategui@intusurg.com
Subject Device	Name: Intuitive Surgical℠ da Vinci℠ Surgical System and Endowrist℠ Instruments Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Endoscopic Instrument Control System, Endoscopic Instruments, and accessories
Predicate Devices	Intuitive Surgical da Vinci Surgical System and Endoscopic Instruments (legally marketed under K990144 / K002489 / K011002 / K013416 / K021036 / K022574 / K040237 / K043153 / K050005)
Device Description	The da Vinci Surgical System, consists of three integrated sub-systems as follows: Endoscopic Instrument Control System: The Endoscopic Instrument Control System is comprised of two sub-systems - the Surgeon Console, Model IS2000-SSC, and Patient Side Cart, Model IS2000-PSC. While seated at the Surgeon Console, the surgeon controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field. Endoscopic instrument and camera movements are controlled by the surgeon through

Device Description (continued)

use of the Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The endoscopic instruments are held in a fixed position (with respect to the patient) by either two (or optionally three) unique manipulators known as Patient Side Manipulators (PSM), which are located on the Patient Side Cart (PSC). The endoscope is also held in a fixed position (with respect to the patient) by another manipulator, similar to the PSM, known as the Endoscope Camera Manipulator (ECM) and also located on the PSC. The PSM and ECM are attached to surgical arms on the PSC known as Set-up Joint (SUJ) arms. Commands from the Surgeon Console are relayed to the PSC, which is located immediately adjacent to the patient, via a cable. Instrument and endoscope changes are performed by another provider positioned adjacent to the PSC.

Stereo View Endoscopic Vision System: The endoscopic vision system used with the da Vinci Surgical System, also known as Intuitive Surgical Insite® Vision System, Model VS1000, consists of a stereo endoscope, endoscopic camera, and various accessories, including a light source and light guides. The Insite Vision System provides two independent images that are relayed to the viewer located in the Surgeon Console, where they are fused to form a 3-D (or alternatively a 2-D image) image of the surgical field.

Intended Use

The Intuitive Surgical da Vinci Surgical 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 ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. 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.

Comparison to Predicate Device	This 510(k) notification is submitted for design modifications to the Endoscopic Instrument Control System. These modifications affect primarily the PSM, ECM, and the Patient Side Cart in order to enhance ease of use. There are also associated minor changes to the Surgeon Console and endoscopic instruments. The user interface design is essentially identical to the predicate device except for minor modifications to accommodate the aforementioned changes. Device operation, functionality, and methods of use for the subject device are identical to the predicate device. The technology, materials, manufacturing methods, and performance are essentially the same for the predicate device as the subject device. The primary differences are 1) changes to the PSM and ECM form factor and associated electromechanical components; 2) changes to the Patient Side Cart mechanics and circuitry to accommodate the modified PSM and ECM; and 3) changes to the Surgeon Console and software to accommodate the modified Patient Side Cart. Minor mechanical modifications to the endoscopic instruments to interface with the modified PSM are also described.
Technological Characteristics	The technological characteristics of the subject devices are essentially the same as for the predicate devices.
Performance Data	Design analysis and comparison, as well as bench testing and risk analysis activities, have been conducted to confirm that the characteristics of the modified device are substantially equivalent to the predicate devices cited.
Conclusion	Based upon the device's general specifications, intended use, and results of risk analysis and performance testing provided in this pre-market notification, the da Vinci Surgical System described herein has been shown to be substantially equivalent to current legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2005

Mr. Michael H. Yramategui
Director, Regulatory Affairs
Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, California 94086

Re: K050369
Trade/Device Name: Intuitive Surgical da Vinci Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: February 10, 2005
Received: February 14, 2005

Dear Mr. Yramategui:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050369

Device Name: Intuitive Surgical℠ da Vinci℠ Surgical System and Endowrist ℠ Instruments

Indications For Use:

The Intuitive Surgical℠ da Vinci℠ Surgical 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 ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. 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
(Part 21 CFR 801 Subpart D) (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)

[signature]

[illegible] Representative

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