K081137

510(k) Summary

Intuitive Surgical, Inc.
da Vinci Si Surgical System; model IS3000

FEB 18 2009

General Information

Trade name	*Intuitive Surgical® da Vinci® Si™* Surgical System
Product name	Intuitive Surgical da Vinci Si Surgical System
Catalog/Model Number	Model IS3000
Common Name	Endoscopic instrument control system, endoscopic instruments and accessories
Classification	Class II
510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact Person	Nitya Narayanan International Regulatory Project Manager nitya.narayanan@intusurg.com
Manufacturer	Product will be manufactured and distributed by Intuitive Surgical, Inc. - mailing and facility address: Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
Establishment registration number:	2955842
Owner/Operator number:	9028901

Summary of Substantial Equivalence

The Intuitive Surgical da Vinci Si Surgical System (model IS3000) does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed computer-controlled surgical instrument systems that are in commercial distribution, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.

Date: April 18, 2008

Substantially Equivalent Devices

Manufacturer	*Substantially equivalent device*	*510(k)*
Intuitive Surgical, Inc. Sunnyvale, CA	da Vinci S Endoscopic Instrument Control System (Model IS2000, V1.1), Endoscopic instruments and accessories	K050369 K063220

Device Description

The Intuitive Surgical da Vinci Si Surgical System, model IS3000 (also known as the Endoscopic Instrument Control System) is a modification of the existing da Vinci S Surgical System, model IS2000. Essentially, the IS3000 is an updated and enhanced version of the existing IS2000 device. The new IS3000 provides a more intuitive user interface and improved ease-of-use.

Overall, the model IS3000 is a computer-assisted device designed to facilitate complex surgery using a minimally invasive approach. The IS3000 consists of the following 3 main components:

- ***Surgeon Console*** (model SS3000) - is the control center for the IS3000 system. While seated at the surgeon console (outside of the sterile field) and as observed through the console's stereo viewer, the surgeon controls critical aspects of the surgical procedures, including movement of the endoscopic instruments and endoscope within the operative field. Instrument and camera movements are controlled by the surgeon through use of 2 hand-operated controllers residing in the console, and foot pedals at the console's base. These features allow the surgeon to be as dexterous as in "open" surgery, while operating in a minimally invasive environment. The surgeon at the console also has the option to change the surgical view from full screen mode to a multi-image mode, which displays the 3-dimensional (3-D) image of the operative field.

- ***Patient Cart*** (model PS3000) - is the operative component of the surgical system within the sterile field. Its primary function is to support the EndoWrist® instrument arms and camera arm, during surgical procedures.

    - ***EndoWrist Instruments*** are designed to provide surgeons with natural dexterity and a greater range of motion than even the human hand. This allows for greater precision when operating in a minimally invasive environment. EndoWrist instruments, when used with the IS3000 system, are designed to support rapid and precise suturing, dissection and tissue manipulation in surgical procedures. There are no changes to the EndoWrist Instruments in this submission.

- ***Vision System Cart*** (model VS3000) - houses the system's image processing equipment and is operated by a person outside of the sterile field during surgery. The cart provides space for an optional touch screen monitor, as well as ancillary surgical equipment. The cart is also known as *Intuitive Surgical Insite* Vision System (Model VS3000) and consists of a stereo endoscope, endoscopic camera and various accessories, including a light source and light guides. The *Insite* Vision System provides 2 independent images that are relayed to the viewer located in the surgeon console, where they are fused to form a 3-D image (or alternatively 2-D) of the surgical field for the surgeon's reference.

Indications for Use

The *Intuitive Surgical Endoscopic Instrument Control System* (Model IS3000) 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, 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.

Bench/Animal/Clinical Testing

Performance (bench) testing was conducted on the IS3000. All testing yielded acceptable results and was comparable to the predicate device.

The IS3000 complies with applicable portions of the following technical standards, or FDA-recognized consensus standards:

UL/IEC 60601-1:1988, Amendment A1: 1991-11, Amendment A2: 1995 Medical Electrical Equipment - Part 1: General requirements for safety
IEC 60601-1-1:2000, Medical Electrical Equipment - Part 1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2001, Medical Electrical Equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility - requirements and tests
IEC 60601-1-4:2000, Medical Electrical Equipment - Part 1: General requirements for safety; Collateral standard: Programmable electrical medical systems
IEC 60601-2-2:1998, Medical Electrical Equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-2-18:1996, Amendment A1: 2000 Medical Electrical Equipment - Part 2: Particular requirements for the safety of endoscopic equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Intuitive Surgical, Inc.
% Ms. Karen Uyesugi
VP, Clinical and Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

FEB 1 8 2009

Re: K081137
Trade/Device Name: da Vinci Si Surgical System IS3000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: December 23, 2008
Received: January 5, 2009

Dear Ms. Uyesugi:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K081137

Device Name: Intuitive Surgical® *da Vinci Si* Surgical System (IS3000)

Indications For Use: The Intuitive Surgical Endoscopic Instrument Control System (Intuitive Surgical® *da Vinci Si* Surgical System Model IS3000) 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, 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 _____
(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)

Neil R. P. Ogden for MKm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081137