K081207

510(k) SUMMARY

DEC 19 2008

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:

Date	5 December 2008
Submitter	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
ER Number **Owner/Operator**	2955842 9028901
Contact	James Farnworth Director, Regulatory Affairs Direct: 408-523-8687 Fax: 408-523-1390 james.farnworth@intusurg.com
Subject Device	Name: *Intuitive Surgical® da Vinci® S™* Surgical System, Model IS2000, with *da Vinci* Connect™, *da Vinci* OnSite™ 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 S* Surgical System (Model IS2000) with Endoscopic and *EndoWrist* Instruments (legally marketed under K050369 and K063220).
Device Description	The *da Vinci S* Surgical System, Model IS2000 with *da Vinci* Connect and *da Vinci* OnSite, is a minor modification to the existing computer assisted device designed to facilitate complex surgery using minimally invasive approach. An overview of the IS2000 consists of the following three main integrated sub-systems: The Surgeon Console, Model SS2000: The control center of the surgical system, and allows the surgeon to control critical aspects of the surgical procedure (including movement of the endoscopic instruments and endoscope). Instrument and camera movements are controlled by the Master Tool Manipulators (MTM), two hand operated controllers, and foot pedals at the Surgeon Console's base. These allow the surgeon to be as dexterous as in "open" surgery, while operating in a minimally invasive

Device Description (continued)	environment. The surgeon has the option to change the surgical view from full screen mode to a multi-image mode, which displays an optional 3-dimensional High Definition (3-D HD), 3-D, or 2-D standard definition image of the operative field. The Patient Side Cart (PSC, Model PS2000): The operative component of the surgical system within the sterile field. Its primary function is to support the endoscopic instrument arms and camera arm, during surgical procedures. Endoscopic instruments are held in a fixed position (with respect to the patient) by unique Patient Side Manipulators (PSM), and the endoscope is held by the Endoscope Camera Manipulator (ECM). The PSM's 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, via a cable. *InSite*® Vision System (Model VS2000): Houses the system's image processing equipment and is operated by a person outside the sterile field during surgery. The cart provides space for an optional touch screen monitor, as well as ancillary surgical equipment. The VS2000 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 image (or alternatively a 2-D) of the surgical field for the surgeon's reference.
Indications for Use	da Vinci Connect: The da Vinci Connect is an accessory to the da Vinci S Surgical System and is intended for use by trained Surgical proctors to communicate and to provide surgical advice to the operating surgeon when using the da Vinci S Surgical System, Model IS2000. In addition, the Remote Proctor Interface can be used to view surgical procedures related to the use of the da Vinci S Surgical System, Model IS2000. da Vinci OnSite: The da Vinci OnSite is an accessory to the da Vinci S Surgical System and is intended for use by trained Intuitive Surgical Customer Service personnel to obtain da Vinci S Surgical System information for the purpose of diagnosing faults with the da Vinci S Surgical System, Model IS2000.
Comparison to Predicate Device	This 510(k) notification is being submitted for minor design modifications to the Surgeon Console and Vision System Cart of the Endoscopic Instrument Control System, Model IS2000. • *da Vinci* Connect allows a skilled remote proctoring surgeon to

Comparison to Predicate Device (continued)	provide advice to the console surgeon via audio, video or using instructional telestration, during a surgical procedure. • *da Vinci* OnSite allows trained Intuitive Surgical, Inc. Customer Support personnel to obtain system information for the purpose of debugging and diagnosing problems with the system. Minor hardware modifications to the Surgeon Console (SS2000) to support *da Vinci* Connect and *da Vinci* OnSite consists of: • Router, • Workgroup Bridge, • Antenna, • Rear Service Panel Modification to allow connection to hospital ethernet Minor hardware modifications to the Vision System Cart (VS2000) to support *da Vinci* Connect and *da Vinci* OnSite consists of: • a *da Vinci* Connect PC (also known as "Proctor PC") mounted on the Vision System Cart, with customized software. • a Uninterruptable Power Supply (UPS) with a battery backup, connected to an existing Medical Grade Isolation Transformer, for the Proctor PC only. • Rear Panel modification, two (2) additional User Video Input connections, and an Ethernet connector. 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.
Technological Characteristics	The technological characteristics of the subject device are essentially the same as for the predicate device.
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	The *da Vinci S* Surgical System (Model IS2000) is a sophisticated computer assisted device designed to facilitate complex surgery using a minimally invasive approach. The indications for use, remains unchanged from the predicate device. The Intuitive Surgical *da Vinci S* Surgical System with *da Vinci* Connect and *da Vinci* OnSite does not raise any new safety or effectiveness issues and is substantially equivalent to, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Intuitive Surgical, Inc.
% Mr. James Farnworth
Director, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

DEC 19 2008

Re: K081207
Trade/Device Name: Intuitive Surgical® da Vinci® S™ Surgical System, Model IS200, with da Vinci Connect™, da Vinci Onsite™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: December 5, 2008
Received: December 8, 2008

Dear Mr. Farnworth:

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): K081207

Device Name: Intuitive Surgical da Vinci S Surgical System, Model IS2000 with da Vinci OnSite and da Vinci Connect

Indications For Use:

Indications For Use – da Vinci Connect:

The da Vinci Connect is an accessory to the da Vinci S Surgical System and is intended for use by trained Surgical proctors to communicate and to provide surgical advice to the operating surgeon when using the da Vinci S Surgical System, Model IS2000. In addition, the Remote Proctor Interface can be used to view surgical procedures related to the use of the da Vinci S Surgical System, Model IS2000.

Indications For Use – da Vinci OnSite:

The da Vinci OnSite is an accessory to the da Vinci S Surgical System and is intended for use by trained Intuitive Surgical Customer Service personnel to obtain da Vinci S Surgical System information for the purpose of diagnosing faults with the da Vinci S Surgical System, Model IS2000.

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)

Neil R Ogden for mkm

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081207