DEC 1 6 2009

K090993

Section II - 510(k) Summary

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	December 14, 2009
Submitter	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Karen Uyesugi VP, Clinical and Regulatory Affairs Telephone: (408) 523 - 8918 Fax: (408) 523 - 1390 e-mail:karen.uyesugi@intusurg.com
Subject Device	Name: Intuitive Surgical® da Vinci, da Vinci *S*® and da Vinci *Si*® Surgical Systems and EndoWrist Instruments and Accessories. 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 Systems (Models IS1200, IS2000, IS3000) and EndoWrist Instruments and Accessories (legally marketed under: K990144 / K002489 / K011002 / K011281 / K012833 / K013416 / K021036 / K022574 / K040237 / K040948 / K042855 / K043153 / K043288 / K050005 / K050369 / K050404 / K050802 / K060391 / K061260 / K063220 / K081137).
Device Description	This 510(k) is being submitted to request an expansion of the Indications for Use to include transoral otolaryngology surgical procedures. There are no changes in the design, technology, materials, manufacturing, performance, specifications, or method of use for the da Vinci Surgical Systems, EndoWrist Instruments and Accessories associated with this pre-market notification. The da Vinci Surgical Systems (Models IS1200, IS2000, IS3000) consists of two integrated sub-systems as follows: A Surgeon Console and a Patient Side Cart. While seated at the Surgeon Console, the surgeon controls critical aspects of the
Device	

Description (continued)	procedure, including movement of the endoscopic instruments and endoscope within the operative field. The endoscopic instrument and camera movements are controlled by the surgeon through 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 arms 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 arm, similar to the PSM, known as the Endoscope Camera Manipulator (ECM), which is also located on the PSC. Commands from the Surgeon Console are relayed to the PSC, which is located immediately adjacent to the patient, via cables. Instrument and endoscope changes are performed by another individual positioned adjacent to the PSC. Intuitive Surgical Stereo View Endoscopic System: The endoscopic vision system used with the da Vinci Surgical Systems, also known as Intuitive Surgical *Insite®* Vision System, 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 surgeon located at 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 Endoscopic Instrument Control Systems (da Vinci, da Vinci *S*, and da Vinci *Si* Surgical Systems Models IS1200, IS2000, IS3000) are intended to assist in the accurate control of Intuitive Surgical EndoWrist Instruments and Accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic/harmonic 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, delivery and placement of microwave 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 for use by

Intended Use (continued)	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	There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the Intuitive Surgical Endoscopic Instrument Control Systems. The expansion of the labeling to include transoral otolaryngology surgical procedures is based on the da Vinci, da Vinci S Surgical Systems (Models IS1200, IS2000, IS3000) and EndoWrist instruments and accessories being currently cleared for performing a full array of surgical tasks across multidisciplinary surgical specialties, and on a comparison of surgical tasks performed in cleared procedures to those performed in transoral otolaryngology surgical procedures.
Technological Characteristics	The technological characteristics of the subject device are the same as for the predicate device cleared to performed similar surgical tasks in other specialties. A list of surgical tasks involved in completing the typical array of transoral otolaryngology surgical procedures confirms there are no new tasks above and beyond those for which the da Vinci Surgical System (IS1200, IS2000, IS3000) is currently used.
Clinical Data	A multicenter retrospective clinical study has been conducted to confirm the feasibility, efficacy, safety and functional assessment in patients undergoing transoral otolaryngology surgical procedures. Historical controls demonstrate substantial equivalence of robotic assisted transoral procedures to alternative methods of treatment (Open surgery, transoral surgery and chemoradiation treatment).
Conclusion	Based upon the information provided in this pre-market notification, the Intuitive Surgical Endoscopic Instrument Control Systems' (Models IS1200, IS2000, IS3000) use in transoral otolaryngology surgical procedures is substantially equivalent to existing treatment methods of otolaryngology procedures (Open and transoral surgery). The use of the da Vinci Surgical Systems do not raise any new issues of safety or effectiveness.

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.
% Ms. Usha S. Kreaden
Senior Director, Clinical Affairs
1266 Kifer Road
Sunnyvale, California 94086

DEC 16 2009

Re: K090993
Trade/Device Name: Intuitive Surgical® Endoscopic Instrument Control Systems
Regulation Number: 21 CFR 876-1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: December 01, 2009
Received: December 02, 2009

Dear Ms. Kreaden:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Section III - Indications for Use

510(k) Number (if known): K090993

Device Name: *Intuitive Surgical*® Endoscopic Instrument Control Systems

Indications for Use:

The Intuitive Surgical Endoscopic Instrument Control Systems (da Vinci, da Vinci *S and* da Vinci *Si* Surgical Systems Models IS1200, IS2000, IS3000) are intended to assist in the accurate control of *Intuitive Surgical* Endoscopic EndoWrist Instruments and Accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic/harmonic 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, 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 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)

Nick Pyo for mm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090993