JUN 2 6 2002

Section II

510(k) SUMMARY

K021036

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	March 29, 2002
Submitter	Intuitive Surgical 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	David Casal, Ph.D. Vice-President, Clinical, Regulatory and Quality Affairs Telephone: 408-523-2113 Fax: 408-523-1390 e-mail: david_casal@intusurg.com
Subject Device	Classification Class I/II - Gynecologic Laparoscope and Accessories, Electrocautery, Endoscope and Accessories Trade Name Intuitive Surgical® da Vinci™ Surgical System Common Name Endoscopic Instrument Control System, Endoscopic Instruments and Accessories Classification Name Endoscope and Accessories (21 CFR 876.1500) Gynecologic Laparoscope and Accessories (21 CFR 884.1720)
Predicate Devices	da Vinci™ Surgical System (legally marketed under K965001/K990144/K002489/K011002)
Device Description	The *Intuitive Surgical*® Endoscopic Instrument Control System (Model IS1200), also known as the *da Vinci*™ Surgical System, consists of three major integrated sub-systems . A brief description of each of these sub-systems is provided below while a more

Device Description (continued)

comprehensive description of their characteristics is provided in subsequent sections of this document. The major sub-systems are as follows:

Intuitive Surgical® Endoscopic Instrument Control System: This sub-system of the *da Vinci*™ Surgical System is comprised of the Surgeon Console and Patient Side Cart. While seated at the Surgeon Console, the surgeon controls virtually all 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 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), also located on the PSC. Commands from the Surgeon Console are relayed to the PSC, which is located immediately adjacent to the patient, via a cable array. Instrument and endoscope changes are performed by another provider positioned adjacent to the PSC.

Intuitive Surgical Stereo View Endoscopic System: The endoscopic vision system used with the *da Vinci*™ Surgical System, 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 viewer located in the Surgeon Console, where they are fused to form a 3-D (or alternatively a 2-D image) of the surgical field.

Intuitive Surgical® Endoscopic Instruments: The *da Vinci*™ Surgical System is designed to use unique endoscopic instruments utilizing a proprietary architecture conveying movements similar to those of the human wrist. These movements – yaw, pitch, rotation, and insertion/withdrawal - are controlled by the surgeon seated at the Surgeon Console. These endoscopic instruments, many of which are referred to as *EndoWrist*™ endoscopic instruments, include scissors, scalpels, graspers/forceps/pick-ups, needle holders, ultrasonic shears, and electrocautery instruments.

Intended Use

The *Intuitive Surgical*® Endoscopic Instrument Control System (hereinafter referred to as the "*da Vinci*™ System") is intended to assist in the accurate control of *Intuitive Surgical*® endoscopic

	instruments including: rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy, Nissen fundoplication, radical prostatectomy, and general non-cardiac thoracoscopic surgical procedures such as internal mammary artery mobilization. It is intended to be used by trained physicians in an operating room environment. *Intuitive Surgical*® Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.
Comparison to Predicate Device	The *Intuitive Surgical*® *da Vinci*™ Surgical System and Endoscopic Instruments described herein are essentially identical in terms of shape, size, function, activation, and intended use to the predicate Class II endoscopic instrument cited.
Technological Characteristics	The technological characteristics of the subject devices are virtually identical to the predicate devices.
Performance Data	Design analysis and comparison as well as appropriate safety testing confirm that basic functional characteristics are substantially equivalent to the predicate device cited.
Conclusion	Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the *Intuitive Surgical*® *da Vinci*™ Surgical System described herein is substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Intuitive Surgical, Inc
David Casal, Ph.D.
Vice President, Clinical, Regulatory and Quality Affairs
950 Kifer Road
Sunnyvale, California 94086

Re: K021036
Trade Name: Intuitive Surgical® DaVinci Surgical System, Model IS1200
Regulation Number: 876.1500
Regulation Name: Endoscopic instrument control system and Endoscopic instruments
Regulatory Class: II
Product Code: NAY
Dated: March 29, 2002
Received: April 1, 2002

Dear Dr. Casal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021036

Device name: *Intuitive Surgical*® Endoscopic Instrument Control System and Endoscopic Instruments.

Indications for Use:

The *Intuitive Surgical*® Endoscopic Instrument Control System (hereinafter referred to as the "*da Vinci*™ System") is intended to assist in the accurate control of *Intuitive Surgical*® endoscopic instruments including: rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy, Nissen fundoplication, radical prostatectomy, and general non-cardiac thoracoscopic surgical procedures such as internal mammary artery mobilization. It is intended to be used by trained physicians in an operating room environment.

Intuitive Surgical® Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Over-the Counter Use_____

(per 21 CFR §801.109 (Optional Format 1-2-96)

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

510(k) Number K021036