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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: K040237

Applicant Information:

Date Prepared:	January 28, 2004
Name:	Intuitive Surgical, Inc.
Address:	950 Kifer Road Sunnyvale, California 94086
Contact Person:	Usha Kreaden, M.Sc
Phone Number:	(408) 523-2140
Facsimile Number:	(408) 523-1390
E-mail:	usha.kreaden@intusurg.com

Device Information:

Classification/Name:	Class II Endoscope and Accessories (21 CFR §876.1500) Gynecologic Laparoscope and Accessories (21 CFR §884.1720
Trade Name:	Intuitive Surgical® da Vinci™ Endoscopic Instrument Control System and Endoscopic Instruments or da Vinci™ Surgical System
Common Name:	Endoscopic Instruments, Control System and Accessories

Predicate Devices:

Substantial equivalence data for the Intuitive Surgical® da Vinci™ Surgical System and Endoscopic Instruments were provided in the original pre-market notifications (K022574, K021036, K011002, K002489, K990144, K965001).

Device Description:

The working ends and elements of the Intuitive Surgical® da Vinci™ Surgical System, Endoscopic Instruments and Accessories are essentially identical in function, size and shape to the predicate devices referenced. They represent standard embodiments of

standard surgical tools, which have been modified for use with the Intuitive Surgical® da Vinci™ Surgical System.

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 for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing during general 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 to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Instructions for Use.

Comparison to Predicate Device(s):

The Intuitive Surgical® Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic medical devices previously cited.

***In Vitro* Test Data:**

Design analysis and comparison as well as *in vitro* testing confirm that basic functional characteristics are substantially equivalent to the predicate devices cited.

Summary:

Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical® Endoscopic Instrument Control System has been shown to be substantially equivalent to currently marketed predicate devices.

Intuitive® and Intuitive Surgical® is a registered trademark of Intuitive Surgical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Usha S. Kreaden
Director Clinical
and Regulatory Affairs
Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, California 94086

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Re: K040237
Trade/Device Name: Intuitive Surgical Endoscopic Instrument Control System and Endoscopic Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Code: NAY
Dated: June 9, 2004
Received: June 15, 2004

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 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for 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

Indications for Use

510(k) Number (if known): K040237

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 for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing during general 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 to be used 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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Miriam C. Provost

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

510(k) Number K040237