K050005 1/3 007

JAN 25 2005

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 30, 2004
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Mike Yramategui Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 e-mail: mike.yramategui@intusurg.com
Subject Device	Name: Intuitive Surgical® da Vinci® Surgical System and Endoscopic Instruments Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Endoscopic Instrument, Monopolar Curved Scissors
Predicate Devices	Intuitive Surgical® da Vinci® Surgical System and Endoscopic Instruments (legally marketed under K990144 / K002489 / K011002 / K013416 / K021036 / K022574 / K040237 / K043153)
Device Description	This special 510(k) is being submitted for a modification to the endoscopic instruments to incorporate monopolar electrosurgical capability on an endoscopic curved scissor instrument. This modification affects the instrument only and there are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci® Surgical System. The endoscopic instruments are used with the *da Vinci*® Surgical System which consists of two integrated sub-systems as follows:

Device Description (continued)

Intuitive Surgical® Endoscopic Instrument Control System: This sub-system is comprised of the Surgeon Console and Patient Side Cart. While seated at the Surgeon Console, the surgeon controls 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) and 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 provider positioned adjacent to the PSC.

Intuitive Surgical® Stereo View Endoscopic System: The endoscopic vision system used with the *da Vinci*® Surgical System, 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 viewer located in 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 System 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 ablation probes and accessories 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 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.

Comparison to Predicate Device	The design, technology, materials, manufacturing methods, performance, specifications and methods of use are essentially the same for the Monopolar Curved Scissors as for other Intuitive Surgical® Endoscopic Instruments with the primary difference being that monopolar electrosurgical capability is incorporated into a curved scissor instrument. There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci® Surgical System
Technological Characteristics	The technological characteristics of the subject devices are essentially the same as for the predicate devices.
Performance Data	Design analysis and comparison, as well as bench testing, has been conducted to confirm that basic functional characteristics are substantially equivalent to the predicate devices cited, and that design output meets the design input requirements.
Conclusion	Based upon the technical information, intended use, and performance information provided in this pre-market notification, the da Vinci® Surgical System and Monopolar Curved Scissors described herein has been shown to be substantially equivalent to current legally marketed predicate devices, and the results of the design control process confirm that the design output meets the design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2005

Mr. Michael Yramategui
Director, Regulatory Affairs
Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, California 94086

Re: K050005
Trade/Device Name: Intuitive Surgical® Endoscopic Instrument Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessoreis
Regulatory Class: II
Product Code: NAY
Dated: December 30, 2004
Received: January 3, 2005

Dear Mr. Yramategui :

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost

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):

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

Indications For Use:

The *Intuitive Surgical*® Endoscopic Instrument Control System 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 ablation probes and accessories 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 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)

Miriam C. Provost

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

510(k) Number K050005