

JUN 29 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: K050802

Date June 23, 2005

Submitter Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, CA 94086

ER Number 2955842

Contact Mike Yramategui
Director, Regulatory Affairs
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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 Control System, Endoscopic Instruments and Accessories

Predicate Devices Intuitive Surgical da Vinci Surgical System and Endoscopic Instruments (legally marketed under K990144 / K002489 / K011002 / K012833 / K013416 / K021036 / K022574 / K040237 / K040948 / K043153 / K043288 / K050005 / K050369 / K050404).

Device Description This 510(k) is being submitted for an expansion of the Indications for Use to include pediatric use. There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci Surgical System associated with this pre-market notification.

**Device
Description
(continued)**

The da Vinci Surgical System consists of two integrated sub-systems as follows:

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 urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiomy 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. 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**

There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci Surgical System. The expansion of the labeling to include pediatric use is based on the da Vinci Surgical System and endoscopic instruments being currently cleared for performing a full array of surgical tasks across multidisciplinary surgical specialties in adults, and comparison of use in representative pediatric procedures. This comparison along with a risk assessment and review of field experience and the published literature on pediatric use of da Vinci surgical system establish equivalency and confirm that there are no new issues of safety or effectiveness.

**Technological
Characteristics**

The technological characteristics of the subject device are the same as for the predicate device (da Vinci Surgical System).

**Performance
Data**

Risk analysis and assessment has been conducted to confirm that basic functional characteristics are substantially equivalent to the predicate device without introducing any new issues of safety or effectiveness, and a review of the field experience and published literature provides validation that there are no new issues of safety or effectiveness for performing surgical tasks in representative pediatric surgical procedures.

Conclusion

Based upon the information provided in this pre-market notification, the da Vinci Surgical System described herein has been shown to be substantially equivalent to current legally marketed predicate devices, and the results of the risk analysis and design validation confirm that there are no new issues of safety or effectiveness.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K050802
Trade/Device Name: Intuitive Surgical da Vinci Surgical System and Endoscopic
Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: May 26, 2005
Received: May 31, 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.

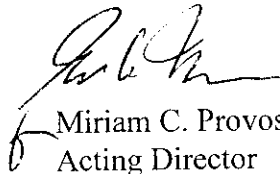
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Miriam C. Provost, Ph.D.
Acting 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): K050802

Device Name: Intuitive Surgical® da Vinci® Surgical System and Endoscopic Instruments

Indications For Use:

The Intuitive Surgical® da Vinci® Surgical 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 urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiomy 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. 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
(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)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices
510(k) Number: K050802

Page 1 of 1