MAY 18 2006

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: K061260

Date	16 May 2006
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Mike Yramategui Senior Director, Regulatory Affairs & Quality Assurance Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 e-mail: mike.yramategui@intusurg.com
Subject Device	Trade Name: *Intuitive Surgical*® *EndoWrist*® PK Dissecting Forceps Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Electrosurgical Instrument, Bipolar Forceps
Predicate Devices	*Intuitive Surgical* Endoscopic Instrument Control Systems *(da Vinci*® Surgical System, Model IS1200 and *da Vinci*® *S*™ Surgical System, Model IS2000) and Endoscopic Instruments – Bipolar Forceps is the predicate devices (legally marketed under K990144, K012833, K050369 and K050802). The Everest (Gyrus) Bipolar Lyons Dissecting Forceps (legally marketed under K031080) is also cited as a secondary predicate, due to this submission being a design modification of the Intuitive Surgical instruments to incorporate features of the Everest / Gyrus Bipolar Lyons Dissecting Forceps as describe in this submission.

Device Description

This SPECIAL 510(k) is being submitted for a design modification to the *Intuitive Surgical* Endoscopic and *EndoWrist* Instruments to incorporate the functionality of the Everest / Gyrus Bipolar Lyons Dissecting Forceps (a Class II, Electrosurgical cutting and coagulation device and accessories) Product Code GEI, under CFR Section 878.4400.

The *Intuitive Surgical EndoWrist* PK Dissecting Forceps (P/N 400214 for the *da Vinci* Surgical System – Model IS1200, and P/N 420214 for the *da Vinci S* Surgical System - Model IS2000) is an endoscopic instrument with a grasping end effector (or grips) to be used in conjunction with the *Intuitive Surgical* Endoscopic Instrument Control Systems (Model IS1200 and IS2000) and a external electrosurgical unit (ESU) provided by Gyrus Medical. The instrument is a reposable bipolar electrosurgical instrument connected to the ESU via a bipolar electrosurgical cable. The ESU can be activated by a foot pedal attached to the ESU itself, and controls the current flow to the grasping end effector of the device. A current passes from the ESU between the grip jaws then back to the generator, allowing for precise tissue coagulation. The instrument end effectors (or grips) are identical to the Everest Bipolar Lyons Dissecting Forceps, and the identical Gyrus connection cable, Gyrus ESU's and Footswitch are used with the EndoWrist PK Dissecting Forceps.

There are no changes to the *Intuitive Surgical* Endoscopic Instrument Control Systems *(da Vinci* Surgical System, Model IS1200 and *da Vinci S* Surgical System, Model IS2000) associated with this pre-market notification. The *da Vinci* and *da Vinci S* Surgical Systems consists of two integrated sub-systems as follows:

Intuitive Surgical Endoscopic Instrument Control System: This sub-system is comprised of the Surgeon Console (SSC) and Patient Side Cart (PSC). 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 PSC. The endoscope is also held in a fixed position (with respect to the patient) by another manipulator, similar to the PSM, known as the Endoscope Camera Manipulator (ECM) and also located on the PSC. The PSM and ECM are attached to surgical arms on the PCS known as Set-up Joint (SUJ) arms. 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 *Intuitive Surgical* Endoscopic Instrument Control 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, vacuum 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 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. 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 *Intuitive Surgical EndoWrist* PK Dissecting Forceps incorporates the functionality of the Everest / Gyrus Bipolar Lyons Dissecting Forceps (a Class II, Electrosurgical cutting and coagulation device and accessories) device in a modification to the *Intuitive Surgical EndoWrist* Bipolar Forceps instrument as cleared under K012833. There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the *Intuitive Surgical* Endoscopic Instrument Control Systems.

Technological Characteristics

The technological characteristics of the subject device (*Intuitive Surgical EndoWrist* PK Dissecting Forceps). are the same as the predicate devices *Intuitive Surgical EndoWrist* BipolarForceps, and Everest / Gyrus Bipolar Lyons Dissecting Forceps).

Performance Data	Design and 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 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 information provided in this pre-market notification, the *Intuitive Surgical EndoWrist* PK Dissecting Forceps described herein is shown to be substantially equivalent to current legally marketed predicate device(s), and the results of the design control process confirm that the design input meets the design output requirements and that that the there are no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2006

Intuitive Surgical, Inc.
% Mr. Mike Yramategui
Senior Director, RA/QA
950 Kifer Road
Sunnyvale, California 94086

Re: K061260
Trade/Device Name: *Intuitive Surgical*® EndoWrist® PK Dissecting Forceps
For use with *Intuitive Surgical*® Endoscope Instrument Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: May 3, 2006
Received: May 5, 2006

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/dsma/dsmamain.html

Sincerely yours,

Herbert Lerner MD

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

Enclosure

Section III

Indications for Use

510(k) Number (if known): K061260

Device Name: *Intuitive Surgical*® *EndoWrist*® PK Dissecting Forceps
For use with *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, vacuum 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 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. 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)

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

510(k) Number K061260