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: K072627

Date	January 30, 2008
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Michael Yramategui Sr. Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 E-mail: mike.yramategui@intusurg.com
Subject Device	Trade Name(s): Intuitive Surgical® *EndoWrist®* Introducer, 5Fr Instrument Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Endoscopic Instrument Control System, Endoscopic Instruments and Accessories Device Class: Intuitive Surgical® *da Vinci®* Surgical System and Endoscopic Instruments: Class II, NAY, System, Surgical, Computer Controlled Instrument

Predicate Devices

Intuitive Surgical *da Vinci*® and *da Vinci*® *S*™ Surgical System and Endoscopic Instruments
(legally marketed under K990144, K002489, K011002, K013416, K021036, K022574, K040237, K43153, K043288, K050404, K050369, K050802 and K063220)

Intuitive Surgical *EndoWrist*® Monopolar Cautery Instrument
(legally marketed under K990144, K013416, K021036, and K050369)

Laserscope Aura XP™ Series Surgical Laser System & Accessories
(legally marketed under K024206)

Lisa Laser RevoLix™ Family of Laser Systems including the RevoLix and RevoLix Jr.
(legally marketed under K051167)

Device Description

This 510(k) is being submitted for a modified *EndoWrist*® instrument, the *EndoWrist* Introducer, 5Fr, to be utilized with surgical lasers delivering energy through flexible laser fibers. This submission also includes the product labeling for the new instrument. There are no changes in the design, technology, materials, manufacturing, performance, specifications or method of use for the *da Vinci* Surgical System or the other predicate devices listed.

***EndoWrist*® Introducer, 5Fr**

The Introducer, 5Fr is used with the *da Vinci* Surgical Systems to hold and position compatible laser fibers used in conjunction with surgical laser systems such as the Laserscope Aura XP or Lisa Laser RevoLix Jr. Laser Systems during indicated surgical procedures. The instrument will also facilitate blunt tissue dissection when the fiber is not present or is retracted into the instrument. The "Introducer, 5Fr" instrument may herein be referred to as the "Introducer" or the "Introducer Instrument".

Similar to currently used minimally invasive endoscopic or laparoscopic surgical instruments, the Introducer Instrument will only hold and position surgical laser fibers and will not directly conduct laser energy.

Device Description (continued)

This Intuitive Surgical instrument is compatible with the previously cleared *da Vinci* and *da Vinci S* Endoscopic Instrument Control Systems Models IS1200 and IS2000.

To address use of the Introducer Instrument with surgical laser systems, a supplemental Instructions for Use sheet is included with each Introducer instrument.

Intended Use

***EndoWrist*® Introducer, 5Fr**

The Intuitive Surgical *EndoWrist* Introducer, 5Fr is intended to be used as a conduit through which compatible surgical laser fibers may be held and directed in conjunction with *da Vinci* and *da Vinci S* surgical systems. At this time, only the following surgical laser systems are compatible for use with the *da Vinci* and *da Vinci S* systems: Lisa Laser Revolix Jr. and Laserscope Aura-XP systems. It may also be used to perform blunt dissection when the laser fiber is retracted or not within the instrument.

Comparison to Predicate Device

***EndoWrist*® Introducer, 5Fr**

The predicate device, the 5mm Monopolar Cautery Instrument, was modified to meet the requirements of the Introducer Instrument. The cautery function has been removed, as the Introducer Instrument is intended to only hold and position compatible laser fibers. Consequently, all electrical contacts, wiring and other components related to the cautery function have been removed. The distal tip lumen was modified to accept a laser fiber and a laser fiber sheath, and the distal tip will no longer accept the cautery accessories, but is now shaped to facilitate blunt dissection of tissue when the laser is not activated.

There is no change in the instrument technology, materials, manufacturing or sterilization processes, common instrument requirements or compatibility with the *da Vinci* Surgical Systems.

Comparison to Predicate Device (continued)	Labeling modification for the Introducer Instrument consists of updated box labeling and the addition of a supplement to the Instrument Instructions For Use which describes the use of the instrument with surgical laser systems. ***da Vinci*® Surgical Systems, Laserscope Aura XP™ Series Surgical Laser System, Lisa Laser RevoLix Jr. Surgical Laser System*** There are no changes in the design, technology, materials, manufacturing, performance, specifications, or method of use for the Intuitive *da Vinci* Surgical Systems and there are no changes intended for surgical laser systems which utilize fibers compatible with the Introducer Instrument, or the fibers themselves. There will be no modifications to labeling for the surgical laser systems or the compatible fibers.
Technological Characteristics	The technological characteristics of the subject devices are identical to the predicate devices.
Performance Data	Design analysis and comparison, as well as bench testing, have been conducted to confirm that basic functional characteristics of the subject devices 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 *EndoWrist*® Introducer, 5Fr has been shown to be substantially equivalent to the current legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2008

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

Re: K072627
Trade/Device Name: *Intuitive Surgical*® Endoscopic Instrument Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: January 10, 2008
Received: January 14, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K072627

Device Name: *Intuitive Surgical® EndoWrist* Introducer, 5Fr

Indications For Use:

The Intuitive Surgical *EndoWrist* Introducer, 5Fr is intended to be used as a conduit through which compatible surgical laser fibers may be held and directed in conjunction with *da Vinci* and *da Vinci S* surgical systems. At this time, only the following surgical laser systems are compatible for use with the *da Vinci* and *da Vinci S* systems: Lisa Laser Revolix Jr. and Laserscope Aura -XP systems. It may also be used to perform blunt dissection when the laser fiber is retracted or not within the instrument.

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, Resto...
and Neurological Devices

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