K013416

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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:**

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| **Date** | October 12, 2001 |
| **Submitter** | Intuitive Surgical<br>1340 West Middlefield Road<br>Mountain View, CA 94043 |
| **ER Number** | 2955842 |
| **Contact** | Michael Yramategui<br>Director, Quality and Regulatory Affairs<br>Telephone: 650-237-7048<br>Fax: 650-526-2060<br>e-mail: mike_yramategui@intusurg.com |
| **New Device** | Name: EndoWrist™ Endoscopic Instruments<br>Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories<br>Common Name: Endoscopic Forceps/Graspers/Needle Drivers/Scissors/Scalpels |
| **Predicate Devices** | da Vinci™ Endoscopic Instrument Control System<br>(legally marketed under K965001/K990144/K002489/K011002) |
| **Device Description** | The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting end effectors to be used with the Intuitive Surgical® da Vinci™ Endoscopic Instrument Control System. These instruments attach to the two instrument manipulator arms on the Intuitive Surgical® Endoscopic Instrument Control System. The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized |

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| **Device Description (continued)** | uses), are provided non-sterile, and must be cleaned and sterilized before use (pre-vacuum autoclave). Single-use scalpel blades are packaged sterile and provided separately. The instruments are programmed for a limited number of uses to ensure reliability and consistent performance, and have non-volatile "add-only" memory that the Instrument Control System decrements after each use.<br><br>The instruments attach to a re-usable, sterilizable adapter on the manipulator arm of the Endoscopic Instrument Control System to provide a barrier between the (sterile) instrument and the (non-sterile) manipulator arm. A mounting surface on the adapter provides a means to secure a sterile drape that covers the arm assembly. This allows instruments to be interchangeable during a procedure, without compromising the sterile barrier. When attached to the manipulator, the instrument is inserted through a cannula mounted to the manipulator.<br><br>All instruments have articulations at the distal end that are controlled by the surgeon. The instrument is the "wrist" of the system and provides four (4) degrees of freedom (wrist pitch, wrist yaw, roll and grip) and the manipulator arm provides an additional three (3) degrees of freedom (insertion, arm pitch, arm yaw) for a total of seven (7) degrees of freedom. The instruments described herein share similar architecture, materials, and manufacturing processes. The primary difference between the instruments is the tip end effector also known as a "grip".. The device and accessories are essentially identical in size and shape to the referenced predicate device, and represent standard embodiments of surgical tools modified for use with the Intuitive Surgical® Endoscopic Instrument Control System. |
| **Intended Use** | Intuitive Surgical® Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing. |
| **Comparison to Predicate Device** | The Intuitive Surgical® EndoWrist™ Endoscopic Instruments described herein are essentially identical in terms of shape, size, function, activation, and intended use to the predicate Class II endoscopic instrument cited. |
| **Technological Characteristics** | The technological characteristics of the subject devices are the same as for the predicate devices. |

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| **Performance Data** | Design analysis and comparison as well as *in vitro* testing confirm that basic functional characteristics are substantially equivalent to the predicate device cited. |
| **Conclusion** | Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical® EndoWrist™ Endoscopic Instruments described herein have been shown to be substantially equivalent to the current legally marketed predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2002

Intuitive Surgical, Inc.
Michael Yramategui
Director, Regulatory and Quality Affairs
1340 West Middlefield Road
Mountain View, California 94043

Re: K013416
Trade Name: EndoWrist™ Endoscopic Instruments
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: NAY
Dated: October 12, 2001
Received: October 15, 2001

Dear Mr. Yramategui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

## Section III

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device name: Intuitive Surgical™ EndoWrist™ Endoscopic Instruments

Indications for Use:

Intuitive Surgical® Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Over-the Counter Use

(per 21 CFR §801.109) (Optional Format 1-2-96)

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

510(k) Number K013416