JUL 31 1997

510(k) SUMMARY

K965001

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: K965001

Applicant Information:

Date Prepared:	June 20, 1997
Name:	Intuitive Surgical, Inc.
Address:	1340 W. Middlefield Road Mountain View, California 94043 415-237-7036
Contact Person:	Michael A. Daniel
Phone Number:	(415) 237-7036
Facsimile Number:	(415) 526-2060

Device Information:

Classification:	Class I / II	Surgical Table and Accessories Endoscope and Accessories Gynecologic Laparoscope and Accessories
Trade Name:	Intuitive Surgical, Endoscopic Instrument Control System Accessories: "Resposable" (limited reuse) Instruments consisting of Retractors and Blunt Dissectors	
Common Name:	Endoscopic Instrument Control System Endoscope and Accessories for Minimally Invasive Surgery	
Classification Name:	Surgical Table and Accessories, Endoscope and Accessories, Gynecologic laparoscope and acces.	21 CFR 878.4960 21 CFR 876.1500 21 CFR 884.1720

Predicate Devices:

The Intuitive Surgical Endoscopic Instrument Control System and Tools are substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. **Computer Motion** AESOP Laparoscope Positioning and Control System
2. **Adronic Devices** Endex (originally "Adept") Instrument Positioning Accessory (IPA)
3. And various atraumatic Class I Exempt surgical instruments including the **US Surgical** Auto Suture+ Endoscopic Fan Retractor (K914190), **Inman Medical Corp.** Endoscopic Blunt Dissector (K933169) and **Medical Perspectives Corp.** Kittner Dissector (K953059)

510(k) SUMMARY

(Continued)

Device Description:

The Intuitive Surgical Endoscopic Instrument Control System is an electro-mechanical device consisting of a Surgical Console including "Master Manipulators", articulated Instrument Control Arms or "Slave Manipulators" and Limited Reuse Tools or end effectors.

Intended Use:

The Intuitive Surgical Endoscopic Instrument Control System is intended for precise and accurate control of selected tracoscopic and laparoscopic instruments including, rigid laparoscopes, blunt endoscopic dissectors, and endoscopic retractors, during thoracoscopic and laparoscopic surgical procedures. It is intended to be used by trained professionals in operating room environments.

Comparison to Predicate Device(s):

The Intuitive Surgical Endoscopic Instrument Control System and Resposable Tools are substantially equivalent to a combination of the Computer Motion AESOP Laparoscope Positioning and Control System, the Adept/Andronic Laparoscopic Positioning and Manipulation System and various other Class I Exempt endoscopic instruments in terms of intended use and basic functionality. The Intuitive System is substantially equivalent to both the Computer Motion and Andronic devices in terms of the capability of precisely moving and controlling endoscopic tools. The Intuitive system is substantially equivalent to the cited predicates in terms of the tissue effects.

***In Vitro* Test Data:**

Design analysis and *in vitro* data confirm that basic functional characteristics are substantially equivalent to the predicate devices sited. Testing included evaluation of reproducibility, hysteresis, and functional adequacy. All data fell well within both internal specification requirements as well as external standard requirements and predicate performance expectations.

Summary:

Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical Endoscopic Instrument Control System has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael A. Daniel
Vice President, Regulatory/Clinical Affairs & Quality Assurance
Intuitive Surgical, Inc.
1340 W. Middlefield Road
Mountain View, California 94304

JUL 31 1997

Re: K965001
Trade Name: Intuitive Surgical Endoscopic Instrument Control System
Regulatory Class: II
Product Code: GCJ
Dated: June 30, 1997
Received: July 1, 1997

Dear Mr. Daniel:

We have reviewed your Section 510(k) 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). 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. The substantial equivalence determination for the Intuitive Surgical Endoscopic Instrument Control System includes use with rigid endoscopes and the following manual surgical instruments only: (1) the Intuitive™ Retractor, (2) the Intuitive™ Blunt Dissector, (3) the Intuitive™ Kitner, and (4) the Intuitive™ Stablizer manual instrument tips.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such

assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, M.D., Ph.D.
Director,
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K965001

Device Name: Intuitive Surgical Endoscopic Instrument Control System

Indications For Use:

The Intuitive Surgical Endoscopic Instrument Control System is intended for accurate control of selected endoscopic instruments including, rigid endoscopes, blunt endoscopic dissectors and endoscopic retractors during thoracoscopic and laparoscopic surgical procedures. It is intended to be used by professionals in operating room environments.

(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 Devices
510(k) Number K965001

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)