NOV 1 6 2001

Section II

510(k) SUMMARY

K012833

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:

Date Prepared: August 21, 2001

Applicant Information:

Name: Intuitive Surgical, Inc.
Address: 1340 W. Middlefield Road
Mountain View, California 94043

Establishment Registration Number: 2955842

Contact Person: Michael Yramategui
Phone Number: (415) 237-7048
Facsimile Number: (415) 526-2060
E-mail: mike_yramategui@intusurg.com

Device Information:

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400)

Trade Name: Intuitive Surgical® Endowrist™ Bipolar Forceps

Common Name: Bipolar Forceps

Predicate Device(s):

United States Surgical	Dexide Bipolar Forceps	K991859
Intuitive Surgical	da Vinci Surgical System	K990144

Device Description:

The Intuitive Surgical® Bipolar Forceps is an endoscopic instrument with a grasping end effector to be used in conjunction with the Intuitive Surgical® Endoscopic Instrument Control System and a standard external electrosurgical generator unit (ESU). It is a resposable electrosurgical instrument connected to the ESU via a bipolar electrosurgical cable. The ESU, which is activated by a foot pedal on the generator itself, controls the current flowing to the grasping end effector (or grips) of the device. A coagulation

current passes from the ESU between the two closely spaced grip electrodes then back to the generator, allowing for precise tissue coagulation. The device is similar in size and shape to other Intuitive Surgical® Endowrist™ Endoscopic Instruments

Intended Use:

The Intuitive Surgical® Bipolar Forceps is intended for use with the da Vinci™ Surgical System to grasp, retract, coagulate and transect soft tissues during endoscopic surgical procedures.

Comparison to Predicate Device:

The Intuitive Surgical® Bipolar Forceps is essentially identical in terms of size, function, activation, and intended use to the predicate Class II endoscopic instrument cited Dexide Bipolar Forceps II, K991859). The primary differences between the subject and predicate devices are the following: 1) the subject device is resposable and 2) the surgeon manipulates and positions the subject device using the Intuitive Surgical® Endoscopic Instrument Control System while the predicate device is handheld.

***In Vitro* Test Data:**

Design analysis and comparison as well as *in vitro* testing confirm that basic functional characteristics are substantially equivalent to the predicate device cited.

Summary:

Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical® Bipolar Forceps has been shown to be substantially equivalent to a currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K012833
Trade/Device Name: Intuitive Surgical Endowrist™ Bipolar Forceps
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 21, 2001
Received: August 23, 2001

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 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 Mark N Melkerson

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

NOV 1 6 2001

0008

Section III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012833

Device name: Intuitive Surgical® Bipolar Forceps

Indications for Use:

The Intuitive Surgical® Bipolar Forceps is intended for use with the da Vinci™ Surgical System to grasp, retract, coagulate and transect soft tissues during endoscopic surgical procedures.

for Mark N Milleman

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

510(k) Number K012833

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use_____

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