K060391

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APR 1 0 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:

Date	13 February 2006
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Mike Yramategui Director, Regulatory and Quality Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 e-mail: mike.yramategui@intusurg.com
Subject Device	Trade Name: Intuitive Surgical *EndoWrist*® Stabilizer Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Cardiovascular Surgical Instrument / Heart Stabilizer
Predicate Devices	Intuitive Surgical *da Vinci*® Surgical System and Endoscopic Instruments is the predicate device (legally marketed under K990144, modified under K050369, and labeling modified under K050802). The Medtronic Octopus TE Tissue Stabilizer, K041338, is listed as a secondary predicate device, due to this submission being a design modification of the Intuitive Surgical instruments to incorporate the features of the Medtronic Octopus TE Tissue Stabilizer as described in this submission.

Device Description

This SPECIAL 510(k) is being submitted for a design modification to the Intuitive Surgical *EndoWrist* Instruments to incorporate the functionality (vacuum stabilization, irrigation) of the Medtronic Octopus TE Tissue Stabilizer (class I, cardiovascular surgical instrument, Product Codes DWS and MWS, under CFR Section 870.4500) on an *EndoWrist* Instrument known as the *EndoWrist* Stabilizer. This modification affects the instrument only, and there are no changes to the *da Vinci* Surgical System associated with this pre-market notification.

The Intuitive Surgical *EndoWrist* Stabilizer is a multiple use instrument similar to existing *EndoWrist* instruments and has the following key features:

- The *EndoWrist* Stabilizer incorporates collapsible "pods" as grips that provide suction based tissue stabilization. The collapsible feature allows the instrument to be used through a 12mm thoracic port.
- A disposable, pre-packaged sterilized tubing assembly known as "*ClearField*" tubing is used to connect the instrument to pressurized irrigation fluid to irrigate the surgical site reducing the amount of blood on the stabilized tissue.
- A disposable, pre-packaged sterilized tubing assembly known as "*CardioVac*" tubing provides vacuum suction to the stabilizer pods from the *Vacuum Source* tubing described below.
- A disposable, pre-packaged sterilized tubing assembly known as "*Vacuum Source*" tubing that connects the *CardioVac* tubing to a canister with a four-meter vacuum hose, and also includes a two-meter vacuum hose (with filter) to connect to a regulated vacuum source.

The Intuitive Surgical *Endowrist* Stabilizer is used with the *da Vinci* Surgical System Model IS2000, which is also known as the *da Vinci*$_{S}$ *S*™ Surgical System. The surgeon sits at a Surgeon Console and controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field through use of the Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The *EndoWrist* Stabilizer is operated in the same way as other Intuitive Surgical *EndoWrist* Instruments, and the surgeon "locks" the stabilizer in position by switching MTM control away from the arm holding the tabilizer instrument by tapping a foot pedal on the Surgeon Console.

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, 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* Stabilizer is identical to existing Intuitive Surgical endoscopic instruments as cleared by FDA under K050369 with the additional functionality of vacuum stabilization and irrigation as incorporated on a Class I tissue stabilizer. The vacuum stabilization and irrigation features are identical to the Medtronic Octopus TE Tissue Stabilizer and accessories cleared by FDA under K041338. There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the *da Vinci* Surgical System.
Technological Characteristics	The technological characteristics of the subject device are the same as for the predicate device(s). The robotic operation and architecture are the same as existing Intuitive Surgical *EndoWrist* Instruments; the stabilizer end effector and irrigation is the same as the Octopus TE Stabilizer (Medtronic).
Performance Data	Design Analysis and comparison, as well as bench testing, has been conducted to confirm that basic functional characteristics are substantially equivalent to the predicate devices cited, and that the design output meets the design input requirements.
Conclusion	Based upon the technical information, intended use, and performance data provided in this pre-market notification, the Intuitive Surgical *EndoWrist* Stabilizer as used with the *da Vinci S* Surgical System described herein, has been shown to be substantially equivalent to current legally marketed predicate devices, and the results of the design control process confirm that the design input meets the design output requirements, and 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

APR 10 2006

Intuitive Surgical, Inc.
c/o Mr. Michael H. Yramategui
Senior Director, Regulatory & Quality Affairs
950 Kifer Road
Sunnyvale, California 94086

Re: K060391
Trade/Device Name: Intuitive Surgical Endowrist® Stabilizer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: March 16, 2006
Received: March 21, 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.

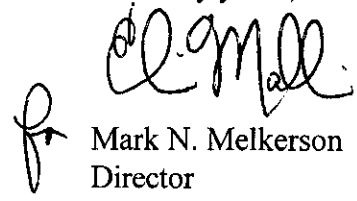
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K060391

Device Name: Intuitive Surgical *Endowrist*® Stabilizer
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, 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

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