Section II

4

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: K070947

Date	February 8, 2008
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Michael Yramategui Sr. Director, Regulatory & Quality Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 E-mail: mike.yramategui@intusurg.com
Subject Device	Trade Name(s): 1. Intuitive Surgical® *da Vinci*® Surgical System and Endoscopic Instruments 2. Intuitive Surgical® *EndoWrist*® Cardiac Probe Grasper 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*® Surgical System and Endoscopic Instruments

(legally marketed underK990144, K002489, K011002, K013416, K021036, K022574, K040237, K43153, K043288, K050404, K050369, K050802 and K063220)

Intuitive Surgical *EndoWrist*® Long Tip Forceps and *EndoWrist* Pericardial Dissector

(legally marketed under K990144, K013416, K021036, and K050369)

CryoCath Inc. SurgiFrost® Surgical CryoAblation System

(legally marketed under K062140, K053436 and K040690)

Device Description

This **special** 510(k) is being submitted for an additional *EndoWrist*® instrument, the Cardiac Probe Grasper, to be utilized with probes and catheters used endoscopically during cardiac ablation procedures. This submission also includes the related minor labeling changes / clarifications on the *da Vinci*® Surgical Systems and *EndoWrist* Instruments. There are no changes in the design, technology, materials, manufacturing, performance, specifications or method of use for the da Vinci Surgical System or the CryoCath SurgiFrost Surgical CryoAblation System.

***EndoWrist*® Cardiac Probe Grasper**

The Cardiac Probe Grasper will be used with the *da Vinci* Surgical Systems to position and hold probes used during ablative cardiac procedures, and will also facilitate precise and delicate blunt dissection of the pericardial reflections at the superior vena cava (SVC) and inferior vena cava (IVC).

This Intuitive Surgical instrument will be compatible with the previously approved *da Vinci* Endoscopic Instrument Control Systems Models IS1200 and IS2000.

To address use of the Cardiac Probe Grasper with cardiac ablation probes, an Instructions for Use addendum sheet will be included with the general IFU for instruments that are compatible with the specified probes.

Device Description (continued)

***da Vinci*® Surgical Systems**

The *da Vinci* Surgical Systems consist of two integrated sub-systems as follows:
Intuitive Surgical® Endoscopic Instrument Control System: This sub-system is comprised of the Surgeon Console and Patient Side Cart. While seated at the Surgeon Console, the surgeon is able to view the surgical field and control critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within that field. Movements are controlled by the surgeon through use of Master Tool Manipulators (MTMs), two hand-operated mechanisms residing within the Surgeon Console.

The *EndoWrist*® endoscopic instruments, stereo endoscope and camera attach to surgical arms located on the Patient Side Cart (PSC). The endoscopic instruments attach to arms known as Patient Side Manipulators (PSM). Another arm, known as the Endoscope Camera Manipulator (ECM), holds the stereo endoscope and camera. Commands from the Surgeon Console are relayed to the PSC, located adjacent to the patient, via various cables. Instrument and endoscope insertions, removals and exchanges are performed by another member of the surgical team positioned adjacent to the PSC.

Intuitive Surgical® Stereo View Endoscopic System: The endoscopic vision system used with the *da Vinci*® Surgical System, also known as the InSite® Vision System, consists of a stereo endoscope, endoscopic camera, and accessories including a light source and light guides. The InSite Vision System provides two independent images that are relayed to the viewer located in the Surgeon Console, where they are fused to form a 3-D (or alternatively a 2-D) image of the surgical field. Additional monitors may be supplied by the user to allow other members of the surgical team to view the procedure.

Intended Use

***EndoWrist*® Cardiac Probe Grasper**

EndoWrist Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

Intended Use (continued)

The Cardiac Probe Grasper is an addition to the *EndoWrist* Instrument family, and there are no changes to be made in the intended use of the device.

***da Vinci*® Surgical Systems**

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 and cryogenic ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecological laparoscopic surgical procedures, general cardiovascular and 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.

This minor labeling change is a clarification within the currently cleared indications for use, and does not alter the intended use of the device.

Comparison to Predicate Device

***EndoWrist*® Cardiac Probe Grasper**

The design of the predicate devices' distal end effectors, or grips, was modified in order to better grasp and manipulate cardiac ablation probes. There will be no change in the instrument technology, materials, manufacturing or sterilization processes, requirements or compatibility with the *da Vinci* Surgical Systems.

Comparison to Predicate Device (continued)	Labeling modification for the Cardiac Probe Grasper will consist of new box labeling and a supplement to the Instrument Instructions For Use describing the use of the instrument with specified cardiac ablation probes. ***da Vinci*® Surgical Systems, CryoCath CryoAblation System** There are no changes in the design, technology, materials, manufacturing, performance, specifications, or method of use for either the Intuitive *da Vinci* Surgical Systems or the SurgiFrost® Surgical CryoAblation System. The only modification consists of an update to the Indication statement which provides a clarification of tasks that can be performed with the *da Vinci* Surgical Systems to add delivery and placement of cryogenic ablation probes. There will be no modifications to CryoCath SurgiFrost labeling. The use of the *da Vinci* Surgical System to deliver and place the SurgiFrost probe is equivalent to the currently cleared practice of using conventional minimally invasive surgical instruments. This change does not impact the operational characteristics or change the intended use of either device.
Technological Characteristics	The technological characteristics of the subject devices are the same as 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*® Cardiac Probe Grasper instrument and the *da Vinci*® Surgical Systems described herein have been shown to be substantially equivalent to current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

Intuitive Surgical, Inc.
c/o Mr. Michael Yramategui
Senior Director, Regulatory Affairs
950 Kifer Rd.
Sunnyvale, CA 94086

Re: K070947
Trade/Device Name: Intuitive Surgical® da Vinci® Surgical System and Endoscopic Instruments; Intuitive Surgical® EndoWrist® Cardiac Probe Grasper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II (two)
Product Code: NAY, GEI, GEH
Dated: December 10, 2007
Received: December 11, 2007

Dear Mr. Yramategui:

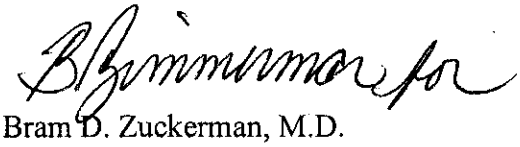
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120. 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section III

Indications for Use

510(k) Number (if known): K070947

Device Name: Intuitive Surgical® *da Vinci*® Surgical System and Endoscopic Instruments
Intuitive Surgical® *EndoWrist*® Cardiac Probe Grasper

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 and cryogenic ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecological laparoscopic surgical procedures, general cardiovascular and 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 Cardiovascular Devices

510(k) Number K070947