OCT - 9 2007 K071405

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	May 18, 2007
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): Probe Holder System Classification Name: Endoscope and Accessories (GCJ, §876.1500) Cannula, manipulator/injector, uterine (LKF,unclassified) Common Name: Holder, Manipulator, Positioner, Arm Device Class: Probe Holder System Class II (GCJ); Unclassified (LKF)

Predicate Devices	Endoboy (K033644) Geyser, SA Zinnanti Uterine Manipulator/Injector (K941458) Zinnanti Surgical Devices, Chatsworth, CA Mediflex Flex Arm (Pre-amendments device) Islandia, NY Thompson Retractor/Device Holder (Pre-amendments device) Traverse City, MI
Device Description	The Intuitive Surgical Probe Holder System is used to mount, position and hold in position uterine manipulators used in laparoscopic surgical procedures. The Probe Holder System can be mounted to standard operating room tables and locked in position allowing surgical devices to be securely held in position for long periods of time. Use of the Probe Holder System frees operating room staff for other activities and reduces fatigue associated with manually maintaining a device in position during surgical procedures. The Probe Holder System consists of two attachment mechanisms: one at its distal terminus for mounting the system to the operating room table and the other at the proximal terminus for securely grasping a surgical device. The mechanism at the distal terminus consists of jointed links, a crossbar and rail clamps while that at the proximal end is a simple mechanism for affixing detachable sterile adaptors that securely grasp a surgical device in the desired position. A handle and foot pedal actuated-mechanism facilitates rapid and secure intra-operative re-positioning of the device by the surgeon as needed. The Probe Holder System remains external to the patient's body at all times and is covered intra-operatively by sterile draping.
Intended Use	The Probe Holder System is intended to assist the surgical staff in mounting, positioning and holding a uterine manipulator during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Comparison to Predicate Device	Based on the comparison of design, technology, materials, manufacturing, performance, specifications, and method of use, the Probe Holder System is substantially equivalent to the previously identified pre-amendment and 510(k) cleared predicate devices.
Technological Characteristics	The technological characteristics of the subject devices are the equivalent to the predicate devices.
Performance Data	Design analysis and testing has 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 available technical information, intended use and performance information provided in this pre-market notification, the Probe Holder System described herein is substantially equivalent to current legally marketed pre-amendment and 510(k) cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2007

Intuitive Surgical, Inc.
% Mr. Michael Yramategui
Sr. Director, Regulatory & Quality Affairs
950 Kifer Road
Sunnyvale, California 94086

Re: K071405
Trade/Device Name: Intuitive Surgical® Endoscopic Instrument Control System
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LKF
Dated: September 6, 2007
Received: September 7, 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.

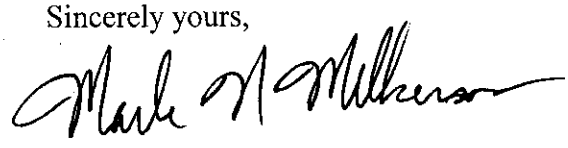
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Section III

Indications for Use

510(k) Number (if known): K071405

Device Name: *Intuitive Surgical*® Endoscopic Instrument Control System

Indications For Use:

The Probe Holder System is intended to assist the surgical staff in mounting, positioning and holding a uterine manipulator during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

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

510(k) Number K071405

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