K082497

Section IV

MAY - 7 2009

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	August 28, 2008
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	James Farnworth Director, Regulatory Affairs Telephone: (408) 523 - 8687 Fax: (408) 523 - 1390 E-mail: james.farnworth@intusurg.com
Subject Device	Trade Name(s): Intuitive Surgical® *EndoWrist®* *One* Hot Shears Instrument 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 *EndoWrist* Monopolar Curved Scissors Instrument, K050005
Device	This 510(k) is being submitted for an endoscopic instrument, the

Description	*EndoWrist One* Hot Shears Instrument, to be used with the Intuitive Surgical *da Vinci* and *da Vinci S* Surgical Systems. The Intuitive Surgical *EndoWrist*® instrument family currently consists of resposable endoscopic tools including the predicate *EndoWrist*® Monopolar Curved Scissors Instrument. The subject Hot Shears instrument has the same intended use as the Monopolar Curved Scissors but is a *single-use* disposable endoscopic tool. This Intuitive Surgical instrument will be compatible with the previously cleared *da Vinci* and *da Vinci S* Endoscopic Instrument Control Systems Models IS1200 and IS2000.
Indications for Use	The *Intuitive Surgical EndoWrist One Hot Shears Instrument* is intended to be used with the da Vinci and da Vinci S Surgical Systems for endoscopic cutting and coagulation of tissue during surgery.
Comparison to Predicate Device	The *EndoWrist One* Hot Shears Instrument is identical in shape, function, activation, and use as the predicate reusable Monopolar Curved Scissors instrument. Specific design and material changes were made in order to create a functionally equivalent instrument intended only for a single surgical procedure. Additionally, the trade name has been updated from *EndoWrist* to *EndoWrist One* to highlight the single-use characteristic of the new instrument. The overall scissor shape and size of the Hot Shears are essentially identical to that of the Monopolar Curved Scissors. The proximal housing and chassis have the same physical dimensions as the predicate instrument, but are provided with a different color scheme and labeling to aid in identification. The predicate Monopolar Curved Scissors instrument uses a sterile removable and disposable Tip Cover accessory which insulates the clevis portion of the distal instrument tip. This Tip Cover is provided as an accessory separate from the instrument. The subject Hot Shears incorporates a Tip Cover with the same function and insulating material directly into its assembly and the user receives the sterile instrument with the tip cover already in place on the distal tip. The single-use Hot Shears Instrument is compatible for use with all electrosurgical generators already cleared for use with the reusable

	Monopolar Curved Scissors instrument. The Hot Shears instrument interfaces with the *da Vinci* and *da Vinci S* surgical systems in an identical manner to the reusable instruments. Both reusable *EndoWrist* instruments and the single use Hot Shears are assigned a specific number of working lives, and the lives are decremented in exactly the same manner by the *da Vinci* Systems. The Hot Shears are assigned only one life, and the systems will not recognize the instrument after that one life is expired, ensuring that it cannot be used again with the *da Vinci* systems. This is identical to the manner in which a reusable instrument expires. The *EndoWrist One* Hot Shears is provided to the customer sterile and packaged in a sealed tray and outer carton. The predicate Monopolar Curved Scissors is provided non-sterile, and the user is responsible for cleaning and sterilizing the instrument prior to each use. Labeling updates for the Hot Shears Instrument consist of new instrument housing markings, new tray and box labeling and a new Instructions For Use.
Technological Characteristics	The technological characteristics of the subject devices are identical to 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 device are substantially equivalent to the predicate device cited, and that design output meets the design input requirements.
Conclusion	Based upon the technical information, Indications for Use and performance information provided in this pre-market notification, the *EndoWrist One* Hot Shears Instrument described herein has been shown to be substantially equivalent to the current legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2009

Intuitive Surgical, Inc.
% Ms. James Farnworth
Director, Regulatory Affairs
950 Kifer Road
Sunnyvale, California 94086

Re: K082497
Trade/Device Name: *Intuitive Surgical® EndoWrist® One* Hot Shears Instrument
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: March 26, 2009
Received: March 27, 2009

Dear Ms. Farnworth:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

for David Krause

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082497

Device Name: *Intuitive Surgical® EndoWrist® One* Hot Shears Instrument

Indications For Use:

The *Intuitive Surgical EndoWrist One Hot Shears Instrument* is intended to be used with the da Vinci and da Vinci S Surgical Systems for endoscopic cutting and coagulation of tissue during surgery.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082497