510(K) SUMMARY
(per 21 CFR 807.92)

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086
Ph: (408) 523-2100
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Official Contact: Brandon Hansen
Sr. Regulatory Affairs Manager

Date Summary Prepared: **August 5, 2011**

Device Name:

Trade Name:	Monopolar Curved Scissors Tip Cover Accessory
Common Name:	Endoscopic Instrument Accessory, Tip Cover Accessory
Classification Name:	Endoscope and Accessories (21 CFR 876.500, Product Code NAY)

Predicate Device: The Monopolar Curved Scissors and Tip Cover Accessory (originally cleared under K050005, current procedures covered under K090993), currently marketed by Intuitive Surgical, Inc. (Sunnyvale, CA).

Device Description: The Monopolar Curved Scissors Tip Cover Accessory is an electrically isolating sleeve that is placed over the distal tip of the Monopolar Curved Scissors. The Tip Cover Accessory acts to isolate the metal parts of the instrument so that only the intended electrode (the scissor blades) is exposed for surgical application.

Indications For Use: The Intuitive Surgical Endoscopic Instrument Control Systems (da Vinci, da Vinci S and da Vinci Si Surgical Systems Models IS1200, IS2000, IS3000) are intended to assist in the accurate control of Intuitive Surgical Endoscopic EndoWrist Instruments and Accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic/harmonic 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, , delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecological laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general 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 (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Instructions for Use.
Technological Characteristics:	The subject device (Monopolar Curved Scissors Tip Cover Accessory) is equivalent in technological characteristics as compared to the predicate device.
Performance Data:	Performance tests (bench tests) were conducted to demonstrate that the subject device is substantially equivalent to the predicate device, and that the design output meets the design input requirements. The results of the testing did not raise any new types of safety or effectiveness questions.
Summary:	The Monopolar Curved Scissors Tip Cover Accessory is substantially equivalent in indications for use and technological characteristics as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT - 7 2011

Intuitive Surgical, Inc.
% Mr. Brandon Hansen
Sr. Regulatory Affairs Manager
1266 Kifer Road
Sunnyvale, California 94086

Re: K112263
Trade/Device Name: Monopolar Curved Scissors Tip Cover Accessory
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 05, 2011
Received: September 12, 2011

Dear Mr. Hansen:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(k) Number if known: K112263

Device Name: Monopolar Curved Scissors Tip Cover Accessory

INDICATIONS FOR USE:

The Intuitive Surgical Endoscopic Instrument Control Systems (da Vinci, da Vinci S and da Vinci Si Surgical Systems Models IS1200, IS2000, IS3000) are intended to assist in the accurate control of Intuitive Surgical Endoscopic EndoWrist Instruments and Accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic/harmonic 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, delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecological laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general 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 (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Instructions for Use.

Prescription Use _X_ (Per 21 CFR 801 Subpart D)
C)

AND/OR

Over-the-Counter Use _____ (Per 21 CFR 807 Subpart

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112263