JAN - 7 2014

510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Brandon Hansen Project Manager, Regulatory Affairs Phone Number: 408-523-7485 Fax Number: 408-523-8907 Email: Brandon.Hansen@intusurg.com
Date Summary Prepared:	September 27, 2013
Trade Name:	Monopolar and Bipolar Cautery Cord
Common Name:	Monopolar/Bipolar Electrosurgical Cord
Classification:	Class II 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories
Product Codes:	GEI
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	Olsen Medical Electrosurgical Cables/Adapters (K111262)

Device Description

The Monopolar and Bipolar Cautery Cords have been designed as an accessory to electrosurgical instruments where monopolar/bipolar electrosurgical cutting and coagulation is desired during surgery. Examples of such instruments include scissors, forceps, and dissectors. The cord connects to the electrosurgical generator on one end and the active instrument on the other end. The Monopolar and Bipolar Cautery Cords are insulated cords with an instrument-mating connector on one end and generator-mating connector on the other end.

Intended Use:

To connect monopolar/bipolar electrosurgical instruments to an electrosurgical generator.

Indications for Use:

The Monopolar and Bipolar Cautery Cords are intended for connecting monopolar/bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency current from the electrosurgical generator to the surgical instrument.

Technological Characteristics:

The Monopolar and Bipolar Cautery Cords are substantially equivalent to the predicate devices, Olsen Medical Electrosurgical Cables/Adapters (K111262) in terms of design, materials, technological characteristics, and intended use.

Performance Data:

Performance test data demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The testing conducted consisted of dimensional measurements, mechanical and functional verification, electrical safety, and use in simulated surgical procedures.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, Monopolar and Bipolar Cautery Cords are substantially equivalent to the predicate devices, the Olsen Medical Electrosurgical Cables/Adapters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 7, 2014

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

Re: K133167
Trade/Device Name: Monopolar and Bipolar Cautery Cords
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 6, 2013
Received: November 7, 2013

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number if known: K133167

Device Name: Monopolar and Bipolar Cautery Cords

INDICATION FOR USE:

The Monopolar and Bipolar Cautery Cords are intended for connecting monopolar/bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency current from the electrosurgical generator to the surgical instrument.

Prescription Use _X_ AND/OR Over-the-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 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)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003490 56
Date: 2013.12.23 07:04:21 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K133167