510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Date	February 12, 2013
Submitter	*Intuitive Surgical, Inc.* 1266 Kifer Road Sunnyvale, CA 94086
Contact	Cherece L. Jones Sr. Regulatory Affairs Specialist Telephone: (408) 523 - 6925 Fax: (408) 523 - 8907 e-mail: cherece.jones@intusurg.com
Subject Device	Trade Name: Connect™ for *da Vinci*® Surgical System(s) Common Name: System, surgical, computer controlled instrument Classification Name: Endoscope and Accessories, 21 CFR 876.1500
Predicate Devices	*Intuitive Surgical*® *da Vinci*® *S*™ Surgical System, Model IS2000 with *da Vinci OnSite*™ and *da Vinci* Connect™ (legally marketed under K081207). *Intuitive Surgical*® *da Vinci*® *S*™ Surgical System, Model IS2000 with Connect™ *OnSite*™ and Wireless Connectivity Option (legally marketed under K101581).
Device Description	Connect is a software accessory, with a Remote Proctor Interface, intended for use by trained surgical proctors to communicate and provide surgical advice to operating surgeons when using the *da Vinci* Surgical System. By using the Remote Proctor Interface, proctors can also view *da Vinci* Surgical Procedures. Communication can be established through either a wired or

	wireless Ethernet connection between the *da Vinci* Surgical System(s) and the hospital's Internet Protocol (IP) infrastructure. The modified Connect software developed by ISI has the following capabilities: • Bi-directional audio • Video from the OR to the RPI • Enable/Disable connection on the *da Vinci* Touchscreen • Image selection from RPI • Remote Telestration • Remote Pointer
Indications for Use	Connect™ for *da Vinci*® Surgical System(s) is an accessory intended for use by trained surgical proctors to (1) communicate and provide surgical advice to the operating surgeon when using *da Vinci* Surgical System(s) and (2) view surgical procedures related to the use of *da Vinci* Surgical System(s) using the Remote Proctor Interface. The wireless connectivity option provides a suitable alternative for the wired Ethernet connection between the *da Vinci* Surgical System(s) and the hospital's Internet Protocol (IP) infrastructure.
Technological Characteristics	The fundamental technological characteristics of the subject device are identical to the predicate device(s). Both the subject and predicate device(s): • encode audio and video for transport over the internet, and • utilize the embedded *da Vinci* system software to facilitate Connect's interaction with the system.
Performance Data	Software Verification Testing and Validation Testing was performed to confirm that the modified Connect accessory performed as intended and that changes made to the software had no adverse impact on the functionality of the system. All test cases met requirements demonstrating that the subject device performed as expected.
Conclusion	The modified Connect accessory has the same Intended Use and technological characteristics and similar Indications for Use and functional characteristics as the predicate devices (K081207 and

K101581).
The Risk analysis did not identify any new issues related to the safety and effectiveness of the device. In addition, verification and validation results demonstrate that the modified software performs as expected and in accordance to the functional specification, thereby also supporting that the Connect accessory is substantially equivalent to the predicate devices.

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

Intuitive Surgical, Incorporated
% Ms. Cherece L. Jones
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

February 14, 2013

Re: K123840
Trade/Device Name: Connect ™ for da Vinci® Surgical System(s)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: January 31, 2013
Received: February 01, 2013

Dear Ms. Jones:

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,

Peter D. Rumm -S

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

Enclosure

INDICATIONS FOR USE

510(k) Number if known: K123840

Device Name: Connect™ for *da Vinci®* Surgical System(s)

Connect™ for *da Vinci®* Surgical System(s) is an accessory intended for use by trained surgical proctors to (1) communicate and provide surgical advice to the operating surgeon when using *da Vinci* Surgical System(s) and (2) view surgical procedures related to the use of *da Vinci* Surgical System(s) using the Remote Proctor Interface. The wireless connectivity option provides a suitable alternative for the wired Ethernet connection between the *da Vinci* Surgical System(s) and the hospital's Internet Protocol (IP) infrastructure.

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

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -S, 0.9.2342.19200300.100.1.1=13003690056
Date: 2013.02.20 08:25:27 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number ___K123840_____