K121921

OCT 25 2012

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	June 29, 2012
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 - 1390 e-mail: cherece.jones@intusurg.com
Subject Device	Trade Name: *Intuitive Surgical*® OnSite™ *for da Vinci*® Surgical Systems Common Name: Endoscopic Instrument Control System, Endoscopic Instruments, and Accessories Classification Name: General and Plastic Surgery
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	OnSite is a software accessory compatible with *da Vinci* Surgical Systems and allows *Intuitive Surgical*, Inc. (ISI) personnel to remotely, through either a wired or wireless Ethernet connection between the *da Vinci* Surgical System and the hospital's Internet Protocol (IP) infrastructure:

	Protocol (IP) infrastructure: • Obtain system information for the purpose of diagnosing faults • Enable/disable features including configuration updates
Intended Use	OnSite for *da Vinci* Surgical Systems is an accessory intended for use by trained *Intuitive Surgical* Field Service personnel for troubleshooting and servicing *da Vinci* Surgical Systems through either a wired or wireless Ethernet connection between the *da Vinci* Surgical System and the hospital's Internet Protocol (IP) infrastructure.
Technological Characteristics	The technological characteristics of the subject device are identical to the predicate devices.
Performance Data	Software Verification Testing and *In Vitro* Validation Testing were conducted to confirm that the new OnSite device performed as intended and that the proposed software changes had no adverse impact on the functionality of the *da Vinci* Surgical System. All test cases successfully passed demonstrating that the subject device is substantially equivalent to the predicate devices.
Conclusion	The modified OnSite software has the same Intended Use, device design and technological characteristics as the predicate devices (K081207 and K101581). Performance data supports that the OnSite software, with expanded capabilities, is substantially equivalent to the predicate devices in terms of safety and effectiveness.

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 25 2012

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

Re: K121921
Trade/Device Name: Intuitive Surgical® OnSite™ *for da Vinci®* Surgical Systems
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: October 11, 2012
Received: October 12, 2012

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,

Mark N. Melkerson
Director
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: K121921

Device Name: Intuitive Surgical® OnSite™ *for da Vinci*® Surgical Systems

OnSite for *da Vinci* Surgical Systems is an accessory indicated for use by trained *Intuitive Surgical* Field Service personnel to: (1) obtain system information for the purpose of diagnosing faults, (2) remotely enable/disable features including configuration updates through either a wired or wireless Ethernet connection between the *da Vinci* Surgical System 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)

for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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