K101077 Page 1 of 2

FEB - 4 2011

INTUITIVE SURGICAL

*Taking surgery beyond the limits of the human hand.*

# 510(k) Summary
**(As Required by 21 CFR 807.92(c))**

April 16, 2010


**Submitter:** Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

**Official Contact:** Karen Uyesugi
Vice President, Clinical and Regulatory Affairs
Ph: 408-523-8918
Fax: 408-523-1390
karen.uyesugi@intusurg.com


***Trade Name:*** Intuitive Surgical da Vinci® Fluorescence Imaging Vision System

**Common Name:** system, surgical, computer controlled instrument

**Product Code:** NAY (GCJ/IZI)

**Classification:** endoscope and accessories, 21 CFR 876.1500

**Predicate Devices:** Intuitive Surgical da Vinci® S Surgical System: Model IS3000 (K081137)
Novadaq Spy Scope Intra-operative Operating System (K091515)

**Device Description:** The Intuitive Surgical da Vinci® Fluorescence Imaging Vision System is an endoscopic imaging system for high definition (HD) visible light and near-infrared fluorescence imaging during minimally invasive surgery. The Intuitive Surgical da Vinci® Fluorescence Imaging Vision System is a variation of the Intuitive Surgical da Vinci® S Surgical System: Model IS3000 (K081137) with the following modified/additional components:

- 12mm endoscopes (0 degree or 30 degree) optimized for NIR fluorescence imaging in addition to VIS imaging.
- A 3D High Definition stereoscopic camera head optimized for NIR fluorescence imaging in addition to VIS imaging.
- A new illuminator for use with the existing video processor unit, and
- A Fluorescence Imaging Kit (IndoCyanine Green (ICG) fluorescence imaging agent, aqueous solvent, and syringe trays)

INTUITIVE SURGICAL

*Extending surgery beyond the limits of the human hand™*

**Intended Use/Indications for Use:** The da Vinci® Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci® Fluorescence Imaging Vision System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infra-red imaging.

**Technological Characteristics:** The da Vinci® Fluorescence Imaging Vision System is equivalent to the predicate devices in terms of its indications for use, design, technology and performance specifications.

**Performance Data:** Verification and validation were performed on the da Vinci® Fluorescence Imaging Vision System to evaluate the device requirements/specifications and to demonstrate that they are substantially equivalent to the predicate devices (da Vinci® Si Surgical System: Model IS3000 and SPY Scope Intra-operative Imaging System).

The results of verification and validation tests demonstrate that the da Vinci® Fluorescence Imaging Vision System components met their design and performance criteria and are substantially equivalent to the predicate devices.

**Summary:** Based on the indications for use, design, technological characteristics and performance data the da Vinci® Fluorescence Imaging Vision System is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.

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

Intuitive Surgical, Inc.
% Ms. Karen Uyesugi
Vice President, Clinical and Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

FEB - 4 2011

Re: K101077
Trade/Device Name: da Vinci® Fluorescence Imaging Vision System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, NAY, IZI
Dated: January 10, 2011
Received: January 11, 2011

Dear Ms. Uyesugi:

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: K101077

Device Name: da Vinci® Fluorescence Imaging Vision System

**INDICATION FOR USE:**

The da Vinci® Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci® Fluorescence Imaging Vision System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infra-red imaging.

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)

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

510(k) Number K101077