# 510(k) Summary (21 CFR § 807.92(c))

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

**Contact:** Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Regulatory Consultant to Intuitive Surgical
Telephone: 650.343.4813
Fax: 650.343.7822
Email: domecusconsulting@comcast.net

SEP 13 2013

**Date Summary Prepared:** 11 September 2013

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

**Common Name:** Endoscopic Instrument Control System

**Classification Name:** System, Surgical, Computer Controlled Instrument (21 CFR §876.1500)

**Product Code:** GCJ, NAY, IZI

**Equivalent Devices:** Intuitive Surgical *da Vinci* Fluorescence Imaging Vision Systems K101077 (Clearance Date: 04 February 11)

**Device Description:**

This 510(k) is being submitted for a revision to the indications for use to include visualization of extrahepatic biliary ducts with the *da Vinci* Fluorescence Imaging Vision System. There are no changes in the design, technology, materials, manufacturing, performance, specifications or method of use for the cleared *da Vinci* Fluorescence Imaging Vision System. A brief description of the device follows:

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 consists of the following elements in addition to the standard components of the IS3000 *da Vinci* SI Surgical System:

- 12mm and 8.5 mm 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,

- An illuminator for use with the video processor unit, and
- A Fluorescence Imaging Kit [IndoCyanine Green (ICG) fluorescence imaging agent, aqueous solvent, and syringe trays]

**Intended 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, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the *da Vinci* Fluorescence Imaging Vision System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

**Comparison to Predicate Device:**
There are no changes in the design, technology, materials, manufacturing, performance, specifications or method of use related to the proposed revision to the indications for use. The labeling revision to include visualization of specific vessels, namely, "extrahepatic biliary ducts," is equivalent to the cleared general indications for use that allows for visualization of vessels.

**Technological Characteristics:**
The technological characteristics of the subject device are identical to the predicate device that is already cleared for visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging. The route of administration, dosing and excretion of ICG is the same for the general and specific indications for use. Importantly, ICG is taken up almost exclusively by the hepatic parenchymal cells and is secreted entirely into the extrahepatic biliary ducts. As such, imaging of these specific vessels is simply a byproduct of standard ICG fluorescence imaging conducted under the currently cleared general indications for use. In other words, extrahepatic biliary duct visualization is possible after ICG injection for any usage.

**Clinical Data:**
This premarket notification includes the results from a prospective study on 72 subjects undergoing robotic cholecystectomy procedures. In all cases, the operating surgeons were able to identify at least one (1) biliary duct with fluorescence imaging. Based on an independent reviewer assessment of a subset of these cases (N=55), this study demonstrated that at least one extrahepatic biliary duct could be identified in 98.2% of the subjects with an acceptable safety profile. Fluorescence imaging enabled visualization of all three (3) ducts in a significantly higher percentage of cases as compared to standard white light visualization. Additionally, this premarket notification contains published literature on 96 subjects from three (3) different centers that demonstrated consistent visualization of extrahepatic biliary ducts under fluorescence imaging in robotic and non-robotic cholecystectomy surgeries. Data

from a single center US study reporting on 154 consecutive robotic-assisted cholecystectomy cases that utilized fluorescence imaging was also submitted. The data included herein shows a comparable safety and effectiveness profile of extrahepatic biliary duct visualization as compared to white light visualization. Lastly, this data supports substantial equivalence of the specific indications for use ("extrahepatic biliary duct visualization") as compared to the general indications for use that allows for visual assessment of vessels.

**Summary:**

Based on the information provided in this premarket notification, use of the Intuitive Surgical *da Vinci* Fluorescence Imaging Vision System to visualize extrahepatic biliary ducts is substantially equivalent to the device's general indications for use that allows for visual assessment of vessels during endoscopic surgeries. The *da Vinci* Fluorescence Imaging Vision System is intended for adjunctive use only in conjunction with standard white light and, when indicated, intraoperative cholangiography (IOC) for extrahepatic biliary duct visualization. The use of the *da Vinci* Fluorescence Imaging Vision System to visualize extrahepatic biliary ducts during endoscopic procedures does not raise different questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

September 13, 2013

Intuitive Surgical, Inc.
% Cindy Domecus
Regulatory Consultant
1266 Kifer Road, Building 101
Sunnyvale, California 94086-5206

Re: K124031
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: OWN
Dated: August 08, 2013
Received: August 09, 2013

Dear Ms. Domecus:

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 -S

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

Enclosure

# Indications for Use Statement

**510(k) Number if Known:** K124031

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

**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, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

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Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.09.13 14:45:09 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number ____K124031_____