DEC - 8 2011 K112208

510(k) Summary
[As Required by 21 CFR 807.92(c)]

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Brandon Hansen
S. Manager, Regulatory Affairs
408-523-7485 (phone)
408-523-1390 (fax)
brandon.hansen@intusurg.com

Date Summary Prepared: October 26, 2011

Trade Name: Intuitive Surgical da Vinci® Single-Site™ Instruments and Accessories

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

Product Code: NAY, GCJ, GEI

Classification: *Endoscope and Accessories, 21 CFR 876.1500*

Predicate Devices:

- *Intuitive Surgical IS3000 da Vinci Si Surgical System with Instruments and Accessories (K081137)*
- *Covidien SILS™ Port, (cleared under K082619)*
- *Transenterix Spider Surgical Instruments (K091697)*
- *Transenterix Spider Flex Monopolar Hook (K102646)*
- *Transenterix Spider Single Port Surgical Device, Support Arm Accessory (K090902)*

Device Description:

The da Vinci Single-Site Instruments and Accessories are a new set of devices developed by Intuitive Surgical to enable single incision cholecystectomy using the IS3000 *da Vinci* Si Surgical System.

The da Vinci Single-Site Instruments and Accessories consist of semi-rigid shaft instruments, two fixed-shape curved cannulae, an accessory cannula for insertion of manual laparoscopic instruments, a semi-rigid blunt obturator, and a single fascial port (with insufflation tubing and stopcock) for the placement and insertion of multiple cannulae/instruments through a single incision.

P. 1/2

The da Vinci Single-Site Instruments and Accessories include instruments to provide grasping, cautery, cutting, clip ligation and suction/irrigation functions. The instruments are non-wristed (similar to the predicate, laparoscopic instruments).

The da Vinci Single-Site Instruments and Accessories are intended to be used with the existing IS3000 *da Vinci* Si Surgical System.

Intended Use:

The Intuitive Surgical da Vinci Single-Site Instruments and Accessories used with the da Vinci Si Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip- ligation and electrocautery during single incision laparoscopic cholecystectomy with the da Vinci Single Site Instruments and Accessories, including graspers, dissectors, scissors, suction irrigators, monopolar cautery, 5mm curved cannulae, 5mm and 10mm straight cannulae, flexible blunt obturators, and the 5mm Single-Site Port.

Technological Characteristics:

The Intuitive Surgical da Vinci Single-Site Instruments and Accessories are equivalent to the predicate devices in terms of their indications for use and technological characteristics.

Performance Data:

Bench, animal, and clinical data demonstrate that the subject device is substantially equivalent to the predicate devices and that the design output meets the design input requirements. The results of the testing did not raise any new issues of safety or efficacy as compared to the predicate devices.

Summary:

Based on the indications for use, technological characteristics and performance data, the Intuitive Surgical da Vinci Single-Site Instruments and Accessories are substantially equivalent to the predicate devices in terms of safety, effectiveness, 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

DEC - 8 2011

Intuitive Surgical, Inc.
% Ms. Melissa Gonzalez
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K112208
Trade/Device Name: Intuitive Surgical da Vinci® Single-Site™ Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: October 26, 2011
Received: October 28, 2011

Dear Ms. Gonzalez:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

> The safety and effectiveness of this device for use in the performance of general laparoscopic abdominal surgery procedures have not been established. This device is only intended to be used for single incision laparoscopic cholecystectomy with the da Vinci Single Site Instruments and the da Vinci Si Surgical System (IS3000).

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health
Food and Drug Administration

Enclosure

510(k) Number if known: K112208

Device Name: *da Vinci® Single-Site™ Instruments and Accessories*

INDICATION FOR USE:

The Intuitive Surgical da Vinci Single-Site Instruments and Accessories used with the da Vinci Si Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip- ligation and electrocautery during single incision laparoscopic cholecystectomy with the da Vinci Single Site Instruments and Accessories, including graspers, dissectors, scissors, suction irrigators, monopolar cautery, 5mm curved cannulae, 5mm and 10mm straight cannulae, flexible blunt obturators, and the 5mm Single-Site Port.

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)

Phil R Ogden for mkm

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

510(k) Number K112208