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

MAY 09 2014

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

Official Contact: Einav Yemini
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Date Summary Prepared: May 1, 2014

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

Common Name: *Endoscope and accessories*

Product Code: NAY, GCJ

Classification: *Endoscope and Accessories, 21 CFR 876.1500*

Predicate Devices: *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories K130726

Device Description:

The *da Vinci Single-Site* Instruments and Accessories consist of semi-rigid shaft instruments, two fixed-shape curved cannulae sets (250 mm and 300 mm lengths), an accessory cannula for insertion of manual laparoscopic instruments, a semi-rigid blunt obturator (250 mm and 300 mm lengths), a rigid 10 mm Blunt Obturator, and a *Single-Site* Port (with insufflation adapter and stopcock) for the placement and insertion of multiple cannulae/instruments through a single incision.

The *da Vinci Single-Site* Instruments and Accessories include instruments to perform manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, and suturing. The *da Vinci Single-Site* Instruments and Accessories are intended to be used with the existing *da Vinci Si* Surgical System (IS3000).

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, electrocautery, and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the *Single-Site* Port.

The indications for use are unchanged from the predicate (K130726).

Technological Characteristics:

The *Single-Site* Port that is the subject of this notification is a functionally equivalent version of the most recently cleared *Single-Site* Port (K130726), which was unchanged from the original *Single-Site* clearance (K112208). The only change to the cleared *da Vinci Single-Site* Instruments and Accessories is a change in material formulation of the *Single-Site* Port. The port material is changing due to material availability. The supplier has changed the material composition to a chemically equivalent material with a slightly different formulation. The *Single-Site* Port is equivalent to the predicate *Single-Site* Port in terms of its technological characteristics, and the intended use is identical.

Performance Data:

Biocompatibility of the new silicone material has been evaluated by a third party lab in compliance with Good Laboratory Practices (GLP) and in accordance with the following guidance and standard:

- FDA's 510(k) Memorandum - #G95-1
- ISO 10993 (Parts 1 - 12): Biological evaluation of medical devices

The *Single-Site* Port is classified as "limited duration contact (< 24 hours), external communicating device (blood path, indirect)" based on its intended use.

Bench and animal testing demonstrated that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The difference in material formulation does not raise any new issues of safety or effectiveness as compared to the predicate device.

Design verification tests were performed on the Single-Site Ports to evaluate the port requirements/specifications and also to demonstrate that it is substantially equivalent to the predicate. Verification testing included:

Category	Test Description	Test Methods
Physical requirements	Configuration	Visual observation
	Dimension	Measurements
	Hardness	Measurements
Equipment Interface requirements	Insufflation equipment	Measurements

Single-Site Ports were tested for reliability through the port's useful life (single use). The test evaluated the ability of the Single-Site Port to function and resist wear during a simulated clinical use. The surgical tasks were designed to simulate actual maneuvers performed with the instruments and camera during minimally invasive surgical operations throughout the expected use of the port. Specifically, the number of repetitions was determined by anticipating the maximum number of such maneuvers performed during a worst case scenario.

Design validation was performed for the subject Single-Site Port to demonstrate its ability to meet its intended use and did not raise any issues of safety or effectiveness. The Single Site Port was placed into the abdominal wall in a porcine model to evaluate the port in live tissue, specifically, the effect of the port on the skin, fascia, fat, etc., that are between the flanges.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the *da Vinci Single-Site* Instruments and Accessories with the modified *Single-Site* Port are substantially equivalent to the predicate device.

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

MAY - 9 2014

Intuitive Surgical, Inc.
Einav Yemini
1266 Kifer Road
Bldg. 101
Sunnyvale, CA 94086-5206 US

Re: K133203
Trade/Device Name: Single-site port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope & Accessories
Regulatory Class: Class II
Product Code: GCJ, NAY
Dated: April 4, 2014
Received: October 21, 2013

Dear Einav Yemini:

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 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. 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.

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 or general gynecological surgery procedures have not been established. This device is only intended to be used for single incision laparoscopic cholecystectomy, benign hysterectomy, and salpingo-oophrectomy 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 L. Foreman -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133203

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

Indications for Use *(Describe)*
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, electrocautery, and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo- oophorectomy with the da Vinci Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the Single-Site Port.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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