Exhibit B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	04/01/2013 - 05/30/2013* FEI NUMBER 3001675293

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gary S. Guthart, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Intuitive Surgical, Inc.	1266 Kifer Rd Bldg 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sunnyvale, CA 94086-5304	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, Intuitive Surgical, Inc. undertook four field actions on 10/10/2011, 10/13/2011, 10/17/2011, and 01/24/2013 without notifying the San Francisco District Recall Coordinator of these actions.

On 10/10/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with suggestions and recommendations for the proper use of instruments with tip covers and for the correct generators that should be used with monopolar instruments. This action was not reported to the San Francisco District Recall Coordinator. This correction was in response to complaints and MDRs for arcing through damaged tip covers that caused patient injury. Between January 2010 and December 2011, Intuitive Surgical, Inc. received 134 complaints and filed 82 MDRs related to tip cover issues.

On 10/13/2011, Intuitive Surgical, Inc. sent out a letter notifying da Vinci clients that the da Vinci surgical systems are not cleared for thyroidectomy indication. This action was not reported to the San Francisco District Recall Coordinator. The thyroidectomy indication was promoted by Intuitive Surgical Inc. after the firm filed a "Letter to File" under the da Vinci general surgery clearance (K990144) but after questions from CDRH, the firm (b) (4) (b) (4) Between July 2009 and October 2011, Intuitive Surgical received 13 complaints and filed 5 MDRs related to thyroidectomies performed with the da Vinci system.

On 10/17/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with information for inspecting instrument cannulas, proper flushing of instruments, and the proper transportation of the da Vinci between buildings. This action was not reported to the San Francisco District Recall Coordinator. Between January 2010 and September 2011, Intuitive Surgical Inc. received 2 complaints related to instrument flush ports and 17 complaints related to cannulas. There were no MDRs directly associated with these complaints, however some of these issues had been previously identified as root causes in other

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complaints that gave rise to MDRs (for example, damage to the integity of a tip cover due to defective cannulas was identified as one of the root causes for arcing that resulted in patient injuries). As such these issues represent a risk to the health of patients.

On 01/24/2013, Intuitive Surgical, Inc. sent out a letter and "da Vinci, da Vinci S, and da Vinci Si Surgical Systems User Manual Addendum for Transoral Surgery (TORS) P/N 552003-02 Rev.B 2012.09" to da Vinci clients to replace "da Vinci, da Vinci S, and da Vinci Si Surgical Systems User Manual Addendum for Transoral Surgery (TORS) P/N 552002-01 Rev.C 2011.04". The letter sent to clients clarified the types of patients and conditions for which daVinci TORS is indicated. For example, the new version of the IFU warns that da Vinci TORS surgery is not indicated for pediatric patients, therefore the vagueness in the previous version of the IFU represented a health risk to pediatric patients.

OBSERVATION 2

Illnesses or injuries that have occurred with use of devices subject to corrections or removals have not been reported.

Specifically, Intuitive Surgical, Inc. failed to report that there were 5 MDRs associated with the field action taken on 10/13/2011 (Thyroidectomy indication withrdawal). The 806 report No. 2955842-101311-004 that was supplied to the San Francisco District Coordinator on 04/11/2013, indicated 0 MDRs in Section 8 on page 3 of 7 of the report. During my inspection of Intuitive Surgical, Inc. 5 MDRs were represented as related to this correction. Intuitive Surgical Inc. failed to report these 5 MDRs on the 806 report provided to the San Francisco District Coordinator on 04/11/2013.

OBSERVATION 3

Procedures for design change have not been adequately established.

Specifically, Intuitive Surgical, Inc. did not document the decision to add a thyroidectomy indication to the da Vinci system general laparoscopy clearance 510(k) No. K990144 through Letter to File rather than through the submission of a new 510(k) application. At the time that this decision was made there were no procedures in place to document this design change issue. Effective as of 04/02/2012, Intuitive Surgical, Inc. has such a procedure in place as illustrated by Section 6.8.4 of Design Control SOP, Document: 854005, that requires that regulatory decisions for design changes be documented using DOP 853226 - Global Regulatory Asessment. However there was no retrospective analysis done to determine how to prevent this error from reoccuring, or to assess if the decision to add a thyroidectomy indication to the da Vinci system general laparoscopy clearance 510(k) No. K990144 through Letter to File, or any other regulatory decisions made for any other design changes done before the addition of this section, should have been reassessed utilizing a DOP 853226 - Global Regulatory Assessment to determine if new regulatory submissions should have been filed for those design changes.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mary R. Hole, Investigator	05/30/2013

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The promotion of the da Vinci thyroidectomy was questioned by the Center for Devices and Radiologic Health, and Intuitive Surgical, Inc. (b) (4)
(b) (4)

OBSERVATION 4

Design input requirements were not adequately documented.

Specifically, the user need for intrasurgical cleaning of surgical instruments was not part of the user needs included in the design of surgical instruments, such as Intuitive Surgical, Inc. Fenestrated Bipolar Forceps Part No. 400205/420205 that are commonly known to need cleaning during surgery. Intuitive Surgical, Inc. has received complaints of arcing of energized surgical instruments as a result of surgeons cleaning off instruments intrasurgically by scraping them across other surgical instruments. In the case of energized surgical instruments, such as Intuitive Surgical, Inc. Monopolar Curved Scissors (MCS) Part No. 420179/400179, the scraping led to tears or holes in protective tip covers that led to arcing that in turn led to injuries to patients.

AMENDMENT 1

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Observation Annotations

Observation 1:	Reported corrected, not verified.	Observation 2:	Reported corrected, not verified.
Observation 3:	Reported corrected, not verified.	Observation 4:	Reported corrected, not verified.

*** DATES OF INSPECTION:**
04/01/2013(Mon), 04/02/2013(Tue), 04/03/2013(Wed), 04/04/2013(Thu), 04/05/2013(Fri), 04/08/2013(Mon), 04/09/2013(Tue), 04/10/2013(Wed), 04/11/2013(Thu), 04/18/2013(Thu), 04/19/2013(Fri), 04/22/2013(Mon), 04/24/2013(Wed), 04/29/2013(Mon), 05/02/2013(Thu), 05/03/2013(Fri), 05/08/2013(Wed), 05/10/2013(Fri), 05/13/2013(Mon), 05/14/2013(Tue), 05/15/2013(Wed), 05/16/2013(Thu), 05/17/2013(Fri), 05/29/2013(Wed), 05/30/2013(Thu)

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