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**Inspections, Compliance, Enforcement, and Criminal Investigations**

**Intuitive Surgical, Inc. 7/16/13**



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94501-7070  
Telephone: (510) 337-6700

**WARNING LETTER**

July 16, 2013

VIA UNITED PARCEL SERVICE

Gary S. Guthart, President and CEO  
Intuitive Surgical, Inc.  
1266 Kifer Road, Bldg 100  
Sunnyvale, CA 94086-5304

Mr. Guthart

During an inspection of your facility located at 1266 Kifer Road, Sunnyvale, CA between April 1, 2013 and May 30, 2013, and investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures computer controlled endoscopic surgical systems and associated accessories. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

The inspection revealed that your da Vinci System IS1000, da Vinci System IS1200, da Vinci System IS2000, da Vinci System IS3000, Tip Cover Accessory, and Cannula 8mm Regular are misbranded devices under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that you failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR 806-Medical Devices; Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to the following:

Failure to submit a written report to FDA within 10 working days of any correction or removal of a device if the correction or removal was initiated to reduce the risk to health posed by the device or to remedy a violation of the act which may present a risk to health as required by 21 CFR 806.10(b).

Examples of these failures include but are not limited to the following:

1. In October 2011, Intuitive Surgical, Inc. initiated a field correction by sending letters to da Vinci Surgical System clients with suggestions and recommendations for the proper use of the

Tip Cover Accessory and for the correct generators that should be used with monopolar instruments. This correction was in response to complaints and medical device reports (MDRs) for arcing through damaged tip covers that caused patient injuries. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1425-2013.

2. In October 2011, Intuitive Surgical, Inc. initiated a separate field correction by sending letters to da Vinci Surgical System clients to notify them that the da Vinci Surgical Systems promoted for thyroidectomy indications is not cleared for that use. You are aware of complaint and MDRs related to thyroidectomies performed with the da Vinci Surgical System. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1426-2013.

3. In October 2011, intuitive Surgical, Inc. initiated a separate field correction by sending letters to da Vinci Surgical System clients with information for inspecting the instrument cannulas, proper flushing of the instruments, and proper transportation of the da Vinci Surgical System between buildings. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1428-2013.

4. In January 2013, Intuitive Surgical, Inc. initiated a field correction by sending letters and replacement user manual addendum titled "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 Surgical System clients. The replacement addendum includes changes to the types of patients and conditions for which da Vinci TORS is indicated, such as warning against use in pediatric patients. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1424-2013.

We have reviewed your response dated June 7, 2013 and find it incomplete and inadequate. Your standard operating procedure titled Field Actions, document 853012, revision T indicates that all corrections, removals, and labeling reiterations will be reviewed with the local district recall coordinator or 3<sup>rd</sup> party expert. We are unable to assess the adequacy of this change as we cannot evaluate the extent of the information that will be submitted to the local FDA recall coordinator. Nor can we assess how you will implement this new requirement in your SOP.

In addition, Section 6.3 of your work instruction titled Regulatory Notifications, document 859179, revision F intended to be used after a determination is made to file a field correction/removal indicates that Class I and Class II actions are to be reported, and Class III actions will be directed to the Head of Regulatory Affairs. This work instruction appears to contradict your Field Actions SOP, document 853012, which indicates that all corrections, removals, and labeling reiterations will be reviewed with the local district recall coordinator or 3<sup>rd</sup> party expert.

The FDA has previously informed you of your firm's correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483 Inspectional Observations issued on December 20, 2002.

A follow-up inspection will be required to assure that your corrections and/or corrective actions are adequate and properly implemented.

The inspection also revealed that your da Vinci System IS1000, da Vinci System IS1200, da Vinci System IS2000, da Vinci System IS3000, Tip Cover Accessory, and Cannula 8mm Regular are

adulterated devices under section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements for devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to the following:

Design input requirements were not adequately documented as required by 21 CFR 820.30(c). Specifically, you informed our investigator that you are aware of patient injuries associated with intraoperative cleaning of energized instruments such as the Monopolar Curved Scissors and Fenestrated Bipolar Scissors as evidenced by at least **(b) (4)** complaints and 82 MDRs during calendar years 2010 and 2011, and 15% of the MDRs reviewed by our investigator. You also informed our investigator that you are aware that cleaning instruments inside patients during surgery is a common practice and have included a label warning in the Instructions-for-Use (IFU) against the practice. When our investigator asked you to provide the design input documentation and design resolution of this known user need you failed to provide the requested documentation.

We have received your response dated June 7, 2013 and find your response to this observation inadequate. Your modification to section 8.1 of document number 823033, revision H in that you are concluding that the IFU adequately consider the known intraoperative cleaning of instruments and the associated risks without going through your design control processes. Your response is also inadequate in that you do not provide a response to the root cause of this critical missing design input in your design documentation.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the awarding of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Lawton W. Lum, Director of Compliance, 1431 Harbor Bay Parkway, Alameda, CA 94502. Refer to the Unique Identification Number 406661 when replying. If you have any questions about the contents of this letter, please contact: Compliance Officer Sergio Chavez at 510-337-6886.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,  
/S/

Elizabeth A. Kage  
Acting District Director

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U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)

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