Inspections, Compliance, Enforcement, and Criminal Investigations

Philips Healthcare 12/20/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

December 20, 2013

WL # 08-14

Mr. Michael L. Magers
General Manager
Philips Healthcare, Inc.
6740 Top Gun St.
San Diego, CA 92121-4114

Dear Mr. Magers:

During an inspection of your firm located in San Diego, California,on July 29 through July 31, 2013, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the InnerCool RTx Endovascular System. Under section 201(h) of the Federal Food, Drug, an Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use i 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.

Our inspection revealed that the InnerCool RTx devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm 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 Part 806 – Reports c Corrections and Removals regulation. Required information regarding the below device correction and removal actions were not sent to FDA within 10 days of initiating a correction or removal as required by 21 CFR 806.10(b):

- In January, 2012, your firm initiated a recall to replace the Main Control Board (MCB) on InnerCool RTx devices that had components from the **(b)(4)** on specific MCB lots. This correction was initiated due to reports of low patient temperature readings which could cause the console to deliver additional heat energy to the patient.

We have reviewed your response, dated August 20, 2013, and find it inadequate. You did not address the above referenced corrections and removals, and did not provide any information to our office regarding the above events. You will need to contact either Mr. Thanh Tran or Ms. Dyana Stone, Recall Coordinators to

provide the appropriate information as required by 21 CFR 806.10(c)(1) for all corrections and or removals that have been conducted by your firm.

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 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 award of contracts

Please notify this office in writing within fifteen (15) 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 o 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: Mr. Blake Bevill, Director, Compliance Branch, Food and Drug Administration, 19701 Fairchild, Irvine, California 92612. If you have any questions about the content of this letter please contact: Dr. William Vitale at 949-608-2919.

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 o the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Alonza E. Cruse, Director
Los Angeles District

Cc:
Hugo Cornejo, Acting Chief
California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue MS 7602
PO Box 997435
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