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# Cardiac Designs Inc. 8/7/15

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Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204-3128

August 7, 2015

**Ref: 2015-DAL-WL-26**

**WARNING LETTER**

**VIA UNITED PARCEL SERVICE**

Karim Morrouche, Chief Executive Officer
Cardiac Designs, Inc.
1104 S. Mays, Suite 219
Round Rock, Texas 78664

Dear Mr. Marrouche:

During an inspection of your firm located in Round Rock, Texason June 16, 2015 through July 2, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer of the ECG Check Application and ECG Check Wireless Lead Cardiac Monitor (ECG Check Monitor). 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.

This inspection revealed that these devices are adulterated within the meaning of 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, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include but are not limited to the following:

1. Failure to establish and maintain design validation procedures to ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions, as required by 21 CFR 820.30(g).

Your firm's "Design Validations" procedure Revision 1 dated May 22, 2015, states software should be tested according to a test plan and requires the results of this software validation to be maintained in the design history file (DHF). Your firm does not have any records demonstrating the ECG Check Application software was validated.

2. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198.

a. Your "Customer Requirements and Complaints" procedure revision 2 dated August 24, 2014, is inadequate. Your firm is currently using a contractor to receive and initially document all communications; however, your complaint handling procedure does not address this practice. Further, your procedure does not address how you will receive, review, and verify complaints are being forwarded from your contract complaint handling company, to conduct the complaint investigations.

b. Your "Customer Requirements and Complaints" procedure revisions 1 and 2, dated May 22, 2013 and August 24, 2014, respectively; require all complaints be documented on your "Customer Complaint Report Form". However, your complaint log showed your firm received at least 87 complaints between April 4, 2014 and June 15, 2015 and these complaints were not documented on your "Customer Complaint Report Form". Further, there are no records showing these complaints were reviewed to determine if an investigation was necessary or if they were evaluated to determine if they were reportable events as defined in 21 CFR 803.

c. On December 16, 2014, your firm received a complaint indicating a possible failure of your ECG Check Monitor and software to detect an abnormal heart

condition. There is no record this complaint was evaluated to determine if it was reportable under 21 CFR 803. In addition, there is no record for this complaint demonstrating the nature and details of the complaint, whether the device failed to meet specifications, or the relationship of the device to the event.

3. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).

Your firm did not follow its "Corrective Action Preventive Action", procedure Revision 1 dated May 22, 2013, requiring your firm to perform and document investigations of corrective and preventive actions (CAPA), and verification that corrective actions taken were effective. For example,

a. CAPA **(b)(4)** dated December 30, 2013 was initiated to address a finding that your devices risk management report incorrectly identified labeling as a mitigation of risk, which your firm identified was not in compliance with a standard (**(b)(4)**) followed by your firm. The CAPA states the risk management report will be updated; however, there is no record your firm verified this correction was completed. In addition, there is no investigation to confirm the causes for the deficiencies or systemic corrections to correct this nonconformance.

b. CAPA **(b)(4)** dated October 10, 2014, was initiated after a third party audit identified your CAPAs were not being fully documented. The CAPA states the corrective action was to correct the deficient CAPA and provide additional training. The CAPA does not contain any record showing this training was conducted. In addition, the CAPA states correction will be verified during internal audits; however, there is no record of these verification activities being conducted. In addition, this CAPA was incorrectly identified as a "preventive action" although the nonconformance had already occurred. Further, the CAPA was ineffective as our investigation identified your corrective and preventive actions are not being fully documented.

Our inspection also revealed that your firm's ECG Check Monitor and application 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 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

1. Failure to develop, maintain and implement written MDR procedures, as required by 21 CFR 803.17.

A. Your "Medical Device & Vigilance Reporting", procedure Revision 1, dated May

22, 2013, does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. Specifically,

1. There are no definitions of what your firm will consider to be a reportable event under 21 CFR Part 803. The exclusion of definitions from 21 CFR 803.3 for the terms “become aware,” “caused or contributed,” “malfunction,” “MDR reportable event,” and “serious injury,” and definitions for the terms “reasonably known” and “reasonably suggests,” found respectively in 21 CFR 803.50(b) and 803.20(c)(1) may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

B. Your “Medical Device & Vigilance Reporting”, procedure Revision 1, dated May 22, 2013, does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

1. How your firm will submit all information reasonably known to it for each event.

2. The procedure does not include the address for where to submit MDR reports: FDA, CDRH, Medical Device Reporting, P. O. Box 3002, Rockville, MD 20847-3002.

Your firm’s procedure includes references to baseline reports. Baseline reports are no longer required and we recommend that all references to a Baseline Report be removed from your firm’s MDR procedure (see: 73 Federal Register Notice 53686, dated September 17, 2008).

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm.

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at ReportabilityReviewTeam@fda.hhs.gov

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. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

In addition, our inspection found your firm has not established a system to ensure all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example,

a. Your firm uses a contract complaint handling company to receive complaints on your ECG Check Monitor and application. Your contract complaint handling firm received approximately 1,147 customer communications and your firm has not reviewed or verified if these communications were being properly received and triaged by your contract complaint handling company. Your firm is responsible for defining the type and extent of control your firm will place on contract service providers. This should include the level of verification and review your firm will conduct to confirm your service providers are meeting your quality requirements. Further, this supplier was not included on your approved supplier list.

b. Your firm contracted a contract manufacturer to conduct design validation and verification testing, and manufacturing of your ECG Check Monitors. During the inspection, neither your firm nor your contract manufacturer was able to provide design validation testing. It is your firm's responsibility to ensure your contract manufactures are adequately performing and documenting the activities you contract them to perform.

As part of your response to this letter, please include a full description of your purchasing control procedures and details of how you plan on correcting the deficiencies to ensure your suppliers are meeting your quality requirements.

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: Dallas District Office, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204. If you have any questions about the contents of this letter, please contact: Jeff R. Wooley at 214-253-5251.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility, products or websites. 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/
Reynaldo R. Rodriguez, Jr.
Dallas District Director

**More in 2015**

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**U.S. Food and Drug Administration**
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