Inspections, Compliance, Enforcement, and Criminal Investigations

Parks Medical Electronics, Inc. 11/27/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 261th Avenue SE, Suite 210
Bothell, WA 98021
Telephone: 425-302-0340
FAX: 425-302-0402

November 27, 2012

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 13-06

Loren E. Parks, CEO
Parks Medical Electronics, Inc.
19460 SW Shaw Street
Aloha, Oregon 97007

WARNING LETTER

Dear Mr. Parks:

During an inspection of your firm located in Aloha, Oregon, on July 30, 2012, through August 17, 2012, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Doppler Ultrasound systems and non-invasive vascular diagnostic devices, including the Flo-Lab 2100-SX model. 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. We received a response from Donald C. Yarnell, Lead Engineering Technician, via email on September 7, 2012, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to your firm. We address this response below, following the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). Specifically, a sales representative for your firm had replacement luer fittings, that are not compatible with other luer fittings, shipped on January 19, 2012, to a user facility and subsequently had the new luer fittings installed on a Flo-Lab 2100-SX. This occurred following the user facility filing a Medwatch report for a misconnection event that occurred on November 1, 2010, and their filing of another Medwatch report on December 29, 2011, for a suspected event that upon further investigation, was determined to not have occurred. This

design change was not validated, or where appropriate, verified, reviewed, and approved according to your Modification Process, ENGW031.017, prior to implementation.

2. Failure to establish and maintain adequate requirements, including quality requirements that must be met by suppliers, contractors, and consultants and to define the type and extent of control to be exercised over the product, services, suppliers, contractors and consultants, based on the evaluation results, as required by 21 CFR 820.50(a)(2). For example, you have no established procedures describing documentation to be maintained by independent sales representatives who perform device servicing or receive complaints while in the field.

3. Failure to establish and maintain procedures that ensure records of acceptable suppliers, contractors, and consultants are maintained, as required by 21 CFR 820.50(a)(3). For example, the accessory tubing supplier, **(b)(4)** luer non-compatible fittings supplier **(b)(4)** and six of **(b)(4)** of your independent sales representatives were not listed on your approved supplier list PURC006-001, effective date April 10, 2008.

4. Failure to submit relevant information on identified quality problems, as well as corrective and preventive actions, for management review, as required by 21 CFR 820.100(a)(7). For example, your Lead Engineering Technician stated that identified quality problems, as well as corrective and preventive actions, are not submitted for management review.

5. Failure to establish and maintain procedures for implementing corrective and preventive actions (CAPA) to include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). Specifically, during the inspection your Lead Engineering Technician stated that you are not analyzing sources of quality data including data from technical support calls and failure summaries, nonconformances identified during final quality checks on the Flo-Lab 2100-SX, or any other quality audit reports, quality records, service records, or returned product.

6. Failure to establish and maintain adequate instructions and procedures for performing and verifying that the servicing meets the specified requirements, as required by 21 CFR 820.200(a). For example, your procedure In-Service Process for Flo Lab Systems, ADMC030.001, requires system performance testing at the time of installation; however, you maintain no documentation to verify specified requirements were met.

7. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency, as required by 21 CFR 820.20(c). For example, ADMC005-015, Management Review, states that the CEO chairs the management review meetings. You did not attend the management review meeting on October 18, 2011.

8. Failure of management with executive responsibility to appoint, and document the appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for: (i) ensuring that quality system requirements are effectively established and effectively maintained in accordance with 21 CFR Part 820; and (ii) reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3). Specifically, Quality Manual, ADMQ001.020, identifies the Quality System Administrator position, and the Lead Engineering Technician stated that he is acting in this position, yet this acting appointment has not been documented.

9. Failure to include, or refer to the location of, the primary identification label and labeling for each production unit in the Device History Record (DHR), as required by 21 CFR 820.184(e). For example, your Lead Engineering Technician stated during the inspection that the primary identification label and labeling for each production unit of the Flo-Lab 2100-SX are not maintained in the DHR.

The adequacy of the corrective actions promised in your response dated September 7, 2012, cannot be determined at this time. Although you included in your response several Corrective Action Request (CAR) forms to address the noted violations, the documents were incomplete. Your response lacked procedures or other documentation detailing specifically how your firm would address the violations.

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.

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: Seattle District Office, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021. If you have any questions about the contents of this letter, please contact Lisa Althar, Compliance Officer, at (425) 302-0427.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by the 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/

Charles M. Breen
District Director