U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Padtest, LLC 12/17/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

December 17, 2014

WL# 5-15
Charles V. Dexter, Operations Manager
Padtest, LLC
7345 E Evans Rd Suite #4
Scottsdale, AZ 85260

Dear Mr. Dexter:

During an inspection of your firm located in Scottsdale, Arizona, on September 16, 2014, through October 8, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures PADCHEK™ devices. 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 James Greenwood, Chief Executive Officer, dated October 16, 2014, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, as well as your corrective actions presented to our investigator during the course of the inspection in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, your firm did not have purchasing control procedures in place at the start of our inspection. During the course of the inspection, you provided *Component Acceptance Procedure*, *Revision Level 001* to our investigator. This corrective action is not adequate because it does not meet the requirements of 21 CFR 820.50.

In your firm's October 16, 2014 response, you provided *Purchasing Procedure*, *Revision Level 001*. This response is not adequate. You did not demonstrate how your suppliers have met the requirements your firm has established under this procedure.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). For example, when asked by the investigator, you replied that your firm does not have any design control procedures and has not documented any design control activities.

Your firm's October 16, 2014 response is not adequate. You state you will implement design control procedures by November 12, 2014, but your firm has not provided specific information regarding how you will meet the requirements of 21 CFR 820.30.

3. Failure to establish and maintain procedures for corrective and preventive action, as required by 21 CFR 820.100(a). For example, your firm did not have corrective and preventive action procedures in place at the start of our inspection. During the course of the inspection, you provided *Corrective/Preventive Action Procedure*, *Revision Level 001* to our investigator. We cannot verify this procedure has been implemented.

Your firm's October 16, 2014 response is inadequate. You provided a CAPA form that appears to address corrective and preventive action activities, but did not reference any training for your Corrective and Preventive Action Procedures, or implementation of a CAPA system.

4. A device master record has not been adequately maintained, as required by 21 CFR 820. 181. For example, specifications for the various components of the device were not maintained; software specifications were not maintained; production process specifications and procedures were not maintained; quality assurance procedures and acceptance criteria were not maintained; packaging and labeling specifications were not maintained; and installation, maintenance and servicing procedures and methods were not maintained.

Your firm's October 16, 2014 response is not adequate. You state you will complete a device master record by November 12, 2014, but your firm has not provided specific information regarding how you will meet the requirements of 21 CFR 820. 181.

5. Failure to establish and maintain procedures for acceptance activities as required by 21 CFR 820.80(a). For example, your firm has not established procedures for acceptance of incoming components, and does not maintain procedures or records for on-site installation/release of the PADCHEK™ device.

Your firm's October 16, 2014 response is not adequate. You state you will implement procedures for acceptance activities by November 12, 2014, but did not provide specific information regarding how you will meet the requirements of 820.80(a).

6. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a). For example, when asked by the investigator, you replied that your firm has not defined, documented, and implemented a quality policy and quality objectives. During the course of the inspection, you provided *Padtest Quality Policy*, dated 9/18/14 to our investigator.

Your firm's October 16, 2014 response references this same document. Your corrective actions are not adequate, as we cannot verify this policy has been implemented.

7. Failure to establish procedures for management review, as required by 21 CFR 820.20(c). For example, when asked by the investigator, you replied that your firm has not established procedures for management reviews and you did not maintain documentation that any management reviews were conducted.

Your firm's October 16, 2014 response is not adequate. You provided procedures for management review, and stated a management review would occur no later than January 15 of each calendar year.

8. Failure to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements, and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, when asked by the investigator, you replied that your firm has not established procedures for quality audits and you did not maintain documentation that any quality audits were conducted. During the course of the inspection, you provided *Internal Audit Procedure, Revision Level 001* to our investigator. The procedure references ISO 9001 requirements, but does not reference applicable FDA requirements, including, but not limited to 21 CFR, Sections 820, 803 and 806.

Your firm's October 16, 2014 response is not adequate. You stated your firm would implement quality audit procedures before November 12, 2014, and would perform a quality audit shortly thereafter. You did not reference whether *Internal Audit Procedure, Revision Level 001* or other procedures would be implemented and followed.

9. Failure to establish procedures or instructions for performing servicing activities, as required by 21 CFR 820.200(a). For example, when asked by the investigator, you replied that your firm has not established procedures for performing servicing activities. During the course of the inspection, you provided *Equipment Maintenance Procedure, Revision Level 001* to our investigator. Your firm provided this same procedure in your October 16, 2014 response. These procedures are not adequate, in that they do not appear to ensure the requirements of 21 CFR 820.200 are met.

10. Failure to establish document control procedures, as required by 21 CFR 820.40. For example, when asked by the investigator, you replied that your firm has not established procedures for document control. During the course of the inspection, you provided *Control of Documents Procedure, Revision Level 001* to our investigator. Your firm provided this same procedure in your October 16, 2014 response. Your firm's response is inadequate because we cannot verify this procedure has been implemented.

Our inspection also revealed that your PADCHEK™ ABI/PVR 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 regarding the devices 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 deviations include, but are not limited to:

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

For example, during the inspection, your firm provided the investigator with a document identified as your firm's MDR procedure, titled "Complaint Processing Procedure". Your firm later acknowledged that the procedure was not an MDR procedure and provided a revised procedure titled "Complaint Processing Procedure", Rev. 001, dated: September 18, 2014 to the investigator in an e-mail dated September 22, 2014. After reviewing the procedure, we determined that procedure titled "Complaint Processing Procedure", Rev. 001, dated September 18, 2014, is not an MDR procedure. The procedure describes your firm's processes for "recording customer complaints, analysis, responses, and corrective actions." As written, the procedure does not meet the requirements of 21 CFR 803.17.

We reviewed your firm's response dated October 16, 2014, and conclude that the adequacy of your firm's response cannot be determined at this time. The response did not include an MDR procedure. In order to determine the adequacy of your firm's response, FDA must receive a copy of the MDR procedure for review.

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 (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 (mailto: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.

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 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: Director, Compliance Branch, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612-2506. 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 of 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:
Harlan Loui, Acting Chief
California Department of Public Health
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Attn: FDA Correspondence