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

Moor Instruments Ltd 12/18/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

WARNING LETTER
DEC 18, 2014

VIA UNITED PARCEL SERVICE

Xiabing Huang
Managing Director
Moor Instruments Ltd.
Millwey, Axminster
Devon EX13 5HU
United Kingdom

Dear Mr. Huang:

During an inspection of your firm located at Millwey, Axminster, Devon, United Kingdom on August 18, 2014, through August 21, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures moorVMS-LDF and moorVMS-LDF-HP Laser Doppler Blood Flow Monitor 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 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 you dated September 12, 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, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for validating the device design, as required by 21 CFR 820.30(g). For example, your firm's validation testing for the moorVMS-LDF was not conducted in accordance with your firm's protocol and report, "System Verification and Validation **(b)(4)** Specifically, your firm did not document the raw data and test results to satisfy the following testing requirements: .

a. **(b)(4)** and

b. **(b)(4).**

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address this observation.

2. 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). For example:

a. Your firm's design change procedure does not include requirements for validation or verification of design changes before their implementation.

b. Your firm did not perform validation or, where appropriate, verification of;

i. Design Change Note 1049, **(b)(4);**

ii. Design Change Note 1075, **(b)(4);** and

iii. Design Change Note 798, **(b)(4).**

We reviewed your firm's response and conclude that it is not adequate. Your firm did not address updating its design change procedure to include requirements for performing validation or, where appropriate, verification, of design changes before implementation. In addition, your firm's response did not address whether your firm retrospectively reviewed design changes to ensure that they were adequately validated or verified prior to implementation.

3. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). For example:

a. Your firm does not have rework procedures; and

b. Eight of your firm's nonconformance records (1081,1085, 1090, 1094,1298, 1300, 1307, and 1308) were incomplete, in that these records did not document retesting and reevaluation results after rework, to ensure that the product met its current approved specification.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address rework procedures. In addition, your firm's response did not indicate whether your firm retrospectively reviewed nonconformance files to ensure that retesting and reevaluation results after rework were documented.

4. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure, as required by 21 CFR 820.70(b). For example, your firm completed design change note 798 to modify the moorVMS-LDF device and updated the software from version 1 to version 2. Work instruction procedure, **"(b)(4)**", states that version 1 is uploaded onto the device during the main board testing operation. However, your firm did not update the work instructions to address the software version change.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address this observation.

5. Failure to establish and maintain procedures to ensure that device history records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record, as required by 21 CFR 820.184. For example:

a. Your firm does not have procedures to ensure that DHRs are maintained and manufactured in accordance with the device master record; and

b. DHRs for the moorVMS-LDF do not include the primary identification label and labeling used for each production unit.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address this observation.

6. Failure to establish and maintain procedures for quality audits and 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, your firm's Internal Audit Procedure does not require quality audits to be conducted by individuals who do not have direct responsibility for the matters being audited. During the 2011 and 2012 internal audits, your firm's Quality and Regulatory Representativeaudited matters that were under her direct responsibility, including customer complaints implemented by your firm's Customer Feedback procedure.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address this observation.

Given the serious nature of the violations of the Act, devices, including moor VMS-LDF and moor VMS-LDF-HP Laser Doppler Blood Flow Monitor devices,manufactured by your firm are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

U.S. 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 deviations are reasonably related will not be approved until the violations 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, including 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 action (which must address systemic problems) 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. Please provide a translation of documentation not in English to facilitate our review. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #444667. If you have any questions about the contents of this letter, please contact: Daniel Walter, Chief, Foreign Enforcement Branch at telephone +1 (301) 796-5587, or fax +1 (301) 847-8139.

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 yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

More in Compliance Actions and Activities (/ICECI/EnforcementActions/default.htm)

Warning Letters (/ICECI/EnforcementActions/WarningLetters/default.htm)

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