Inspections, Compliance, Enforcement, and Criminal Investigations

GUANGDONG BIOLIGHT MEDITECH CO., LTD 1/2/13

Department of Health and Human Services

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

JAN 2, 2013

WARNING LETTER

Mr. Jinyuan James Yan
General Manager
Guangdong Biolight Meditech Co., Ltd.
No. 2 Innovation First Road,
Technology Innovation Coast Hi Tech Zone
Zhuhai, China 519085

Dear Mr. Jinyuan James Yan:

During an inspection of your firm located in Zhuhai, Chinaon August 20, 2012, through August 23, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures physiological patient monitors and accessories. 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 11, 2012, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations that was issued to your firm. We address this response below, in relation to each of the noted violations. Your firm's response dated November 6, 2012, to the Form FDA 483 (FDA 483) was not reviewed because it was not received within fifteen business days of issuance of the FDA 483. The response may be evaluated along with any other written material provided in response to the violations cited in this Warning Letter. These violations include, but are not limited to, the following:

1. Failure to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198 (a).

For example:

A. Your firm's Customer Complaint Procedure Doc. No. **(b)(4)** does not ensure that all complaints are evaluated to determine whether the complaints should be filed as Medical Device Reports (MDRs). None of the four complaints reviewed were processed as complaints, or evaluated to determine whether the complaints should be filed as MDRs. Complaint records lacked fields for any evaluation for MDR reporting, investigation results, dates, or replies to complainants. In addition, none of the four complaint records reviewed were handled as complaints per their procedure, nor were any evaluated as to whether the failures met the requirements for MDR reportable events.

B. The distributor's **(b)(4)** logo and contact information is used on the FingerTrip Pulse Oximeter devices manufactured by Guangdong Biolight Meditech. There is no agreement or contract between your firm and the distributor to identify responsibilities regarding complaint handling and MDR reporting. Your firm stated that it was unaware if **(b)(4)** has been handling complaints.

The adequacy of your firm's response dated September 11, 2012, cannot be determined at this time. Your firm intends to conduct an investigation of all previous complaints to determine MDR reportability. All past complainants will be contacted to record their responses as objective evidence. Your firm plans to revise the Customer Complaint Procedure, the Reporting and Notification Control Procedures and conduct training as appropriate. However, your firm did not include documentation or evidence of the correction and the corrective action.

2. Failure to maintain a record of investigations, when an investigation is made by the formally designated unit indentified in paragraph (a) of this section, as required by 21 CFR 820.198(e).

For example: All investigations were not handled consistently in accordance with your firm's complaint handling procedure. All investigations were not recorded on the appropriate Customer Complaint Forms. In addition, there is inconsistent documentation of required complaint information (i.e. the date the complaint was received; the name, address, and phone number of the complainant; device identification and control numbers, etc.).

No response was provided by your firm because this violation was not included as an observation on the FDA 483.

3. Failure to establish and maintain procedures for validating the device design 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).

For example: Your firm's design validation procedures outlined in Section 4.6 of the Design Control Procedure, Doc. No. **(b)(4)** do not ensure that the results of the design validation, including identification of the design, methods, the date, and the individuals performing the validation are documented in the Design History File (DHF). Thirty test records from a clinical study conducted as part of the design validation for the AnyView A8 Monitor were reviewed. The results of the design validation, including the identification of the design, the unit tested, the date, and the individuals performing the validation were not documented. In addition, the investigator noted that a software revision had since occurred; however, your firm admitted that the newer software version had not undergone software validation.

The adequacy of the response dated September 11, 2012, cannot be determined at this time. Your firm stated that it intends to conduct an investigation of all past validation records for products distributed to the U.S. to determine whether re-validation is required. However, your firm did not include documentation or evidence of the correction and the corrective action.

4. Failure to establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f).

For example:

A. Your firm has not confirmed that the design output meets the design input requirements.

i. The investigator asked if the test article identified as AnyView A8 Multi-parameter patient monitor, (serial number: **(b)(4)**), was a prototype or a pilot run unit, and requested to review the component listing of the unit to identify which software version was contained on the unit at the time of the verification testing. Your firm was not able to confirm when or how the unit was manufactured, or what software revision was programmed into the unit at the time of testing.

ii. Your firm used the design verification of the AnyView A8 patient monitors to verify the A6 monitors. No verification activities had been conducted for the A6 patient monitors.

B. The results of the design verification, including identification of the design, methods, the date, and the individuals performing the verification have not been documented in the DHF. The procedures outlined in Section 4.4 of the Design Control Procedure, Doc. No. **(b)(4)**, does not include requirements to ensure that all required data is recorded and retained in the DHF. Specifically:

i. The design verification results for Test Report No. **(b)(4)** for the ANSI/AAMI EC13:2002 Standard did not include identification of the design units tested, or the methods used to perform verification testing.

ii. Test Report No. **(b)(4)** Test for Heart Rate Accuracy did not include documentation of approval for the methods used prior to testing.

iii. No documentation of the approved testing protocol was available in the DHF.

The adequacy of the response dated September 11, 2012, cannot be determined at this time. Your firm stated that it will conduct an investigation of all past verification records for products distributed to the U.S. to determine whether re-verification is required. However, your firm did not include documentation or evidence of the correction and the corrective action.

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

For example:

A. Your firm's Corrective and Preventive Action (CAPA) Control Procedure, Doc. No. **(b)(4)**, does not include requirements for:

i. Analyzing all sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

ii. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device.

iii. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

B. Your firm's procedures indicate that three different CAPA forms can be used:

i. The CAPA and Improvement Record

ii. Customer Complaint Record

iii. CAPA and Nonconformance Record

During the investigator's review of the CAPA files, four CAPAs were found to be documented on form's called "Quality Problem Records", that was not mentioned in your firm's procedure. None of the four CAPA files included documentation of all corrective actions, implementation dates, or effectiveness check information as per your CAPA procedures.

The adequacy of the response dated September 11, 2012, cannot be determined at this time. You firm stated that a retrospective analysis of all historical and open CAPAs will be performed. However, your firm did not include documentation or evidence of the correction and the corrective action.

6. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).

For example: Your firm's Nonconforming Control Procedure, Doc No. **(b)(4)** requires that both nonconforming and conforming product are identified according to the Identification and Traceability Control Procedure, Doc. No. **(b)(4)**. The following observations were made:

A. Printed circuit boards that had not been inspected were packaged in boxes used for conforming products.
B. Units in the service area were not consistently identified as nonconforming.
C. Returned patient monitor units were not clearly identified.
D. Repaired units requiring retesting were re-introduced into the general production population.

The adequacy of the response dated September 11, 2012, cannot be determined at this time. Your firm stated that historical data will be reviewed to determine if nonconforming product was released. However, your firm did not include documentation or evidence of the correction and the corrective action.

7. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e).

For example:

A. Design Control Procedure, Doc. No. **(b)(4)** does not include requirements for ensuring that participants at each design review include representatives of all functions concerned with the design stage being reviewed, an individual who does not have direct responsibility for the design stage being reviewed, and any specialists needed.

B. Design Control Procedure, Doc. No. **(b)(4)** did not specify when formal designated design reviews were required to be held.

i. The investigator asked to review the Design Review Meeting records for the Design Input stage as outlined in **(b)(4)** of the Design Control Procedure, Doc. No. **(b)(4)**. No records for a formal Design Input Review meeting could be found.

ii. The investigator asked to review the Design Review Meeting Records for the Prototype Review (as per **(b)(4)**). No Prototype Design Review Meeting records could be found in the DHF.

iii. No records could be found to show that a design review meeting was held prior to design

transfer (prior to release of the design to market production).

The adequacy of the response dated September 11, 2012, cannot be determined at this time. Your firm stated that all design review records for products distributed to the U.S. will be reviewed to ensure that design reviews were performed at appropriate stages. However, your firm did not include documentation or evidence of the correction and the corrective action.

8. 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, and the requirements of 21 CFR 820, as required by 21 CFR 820.184.

For example: None of the four DHRs reviewed included copies of the primary identification label, and labeling used for each production unit.

The adequacy of the response dated September 11, 2012, cannot be determined at this time. Your firm stated that a retrospective review of all printing records will be conducted. However, your firm did not include documentation or evidence of the correction and the corrective action.

Our inspection also revealed that your firm's 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:

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

For example: After reviewing your firm's MDR procedure titled "Reporting Control Procedure" **(b) (4)**, effective date: June 12, 2012, the following issues were noted:

A. Your firm's MDR procedure 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:

i. The procedure does not reference a process for identifying and evaluating events occurring outside the United States (U.S.) as potentially reportable to FDA. If an event occurs in a foreign country, it may be reportable under the MDR regulation if the event involves a device that is the same or similar to a device that has been cleared or approved for marketing in the U.S. By not considering events that occur outside of the U.S., potentially reportable MDRs may not be identified and evaluated for MDR decision making and submission to FDA as required by 21 CFR 803.50 and 21 CFR 803.53.

ii. There are no definitions of what your firm will consider to be a reportable event under 21 CFR Part 803. To facilitate the correct interpretation of reportable events and to assure the quality of MDR submissions, the procedure should include definitions based on 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).

B. Your firm's MDR procedure does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

i. Instructions for how to obtain and complete the FDA 3500A form.
ii. The circumstances under which your firm must submit initial, 5-day, supplemental or follow-up reports and the requirements for such reports.

iii. 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.

C. Your firm's MDR procedure does not describe how it will address documentation and record-keeping requirements, including:

i. Information that was evaluated to determine if an event was reportable.
ii. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable.
iii. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

We reviewed your firm's response dated September 11, 2012, and conclude that it is not adequate. Your firm's response indicated that it revised its MDR procedure titled "Reporting Control Procedure" **(b)(4)**, effective date: 6/12/2012. However, your firm's revised MDR procedure still does not meet the requirements of 21 CFR 803.17 for the reasons stated above.

If your firm wishes to submit MDR reports via electronic submission it can follow the directions stated at the following URL: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm[1]

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the MDR Policy Branch at 301-796-6670 or by email at ReportabilityReviewTeam@fda.hhs.gov.

In addition, this inspection revealed that your FingerTrip Pulse Oximeter devices are misbranded within the meaning of section 502(b), 21 U.S.C. 352(b), in that the devices are in package form and their labels fail to contain the name and place of business of the manufacturer, packer, or distributor.

For example, your firm's product labeling fails to conspicuously specify your firm's name and place of business, as required by 21 CFR 801.1. Specifically, your firm's name and place of business is not found on the device label of your FingerTrip Pulse Oximeter device.

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. 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, 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 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. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Rm 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993.Refer to CMS case #381918 when replying. If you have any questions about the contents of this letter, please contact: LCDR Joshua Simms, at (301) 796-5599.

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

Page Last Updated: 02/21/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm