Thermedx LLC 4/8/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
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April 08, 2015

Via United Parcel Service

WARNING LETTER
WL-15-448762-14

Douglas L. Carr, President
Thermedx, LLC
31200 Solon Road, Unit 1
Solon, OH 44139-3556

Dear Mr. Carr:

During an inspection of your firm located in Solon, OH on November 19, 2014 through December 11, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures fluid management systems for gynecological and urological use. 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.

Your firm's response dated January 14, 2015 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 will 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 adequately establish procedures for corrective and preventive actions, as required by 21 CFR 820.100(a). Specifically,

Your firm has not taken appropriate corrective actions for identified non-conformities. For example:

a. You initiated CAPA 2013-007 on December 13, 2013 in response to 6 complaints regarding incorrect fluid deficit calculation on the canister of the fluid management device. This same hazard was identified in recall Z-2555-2014 which was classified as a Class II recall. Your design hazard analysis identifies this as your highest severity level of "10". To date, your firm has not implemented any corrective actions to remedy this potential safety concern.

b. Additionally, your firm has made 21 software upgrades since the release of the system, 17 of which were not evaluated for potential correction and removals. All of these software upgrades have been upgraded to all field systems. These software upgrades included fixes for identified hazards such as fluid deficit issues in software revisions G", "L", "N" and "S" all with an assigned severity level of "10".

2. 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 this part, as required by 21 CFR 820.184.

Specifically, a review of 17 device history records for the Thermedx fluid management system showed that 14 of the devices did not meet specification for fluid pressure. According to test procedure instructions TST-00946, Rev I, the pressure measurement on the device should be within 10% of an inline pressure gauge used for testing. Six of the devices did not meet the within 10% specification and 8

devices were not tested. All 14 devices were released by quality.

3. Failure to ensure, where the results of a process cannot be fully verified by subsequent inspection and test, that the process shall be validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 820.75(a).

Specifically, your original master validation plan (Rev A, 9/2010) did not identify the ultrasonic welding or CNC operations at your firm. Your revised plan (Rev B, 11/2014) requires installation qualification (IQ), operational qualification (OQ) and process qualification (PQ) activities for the **(b)(4)** ultrasonic welding process and for the **(b)(4)** CNC machining. You have not performed "OQ" or "PQ" on the CNC process or "OQ" on the **(b)(4)** welders. Additionally, you have not performed OQ or PQ studies on the crimping process used to manufacture wire/terminal connections.

Your PQ validation studies for the **(b)(4)** welding process (used to manufacture the cartridge) were conducted using a set of fixed values for the variables during the welding process. You have deviated from these "fixed" values 5 times since the validation studies with no documented rationale of acceptance or possible ramifications for deviating from the process. According to your Mechanical Engineering of Tech Service, complaints 13-0067, 14-0021 and 14-0057 are possibly attributed to the welding process.

4. Failure to clearly define the type and extent of control to be exercised over suppliers, as required by 21 CFR 820.50(a)(2). Specifically,

a. Purchasing Control Procedures (QSP 7.5) do not clearly describe the criteria for the continuous monitoring of suppliers. The procedures only state that "Approved Supplier shall be routinely monitored by Purchasing and Quality ..." The procedures do not describe how the suppliers will be monitored, how often, acceptable levels of performance or when to place additional controls or disqualify a supplier. Additionally, there is only evidence of some level of supplier monitoring (NCM review) since July 2014 during quality review meetings.

b. According to your procedures for Purchasing Control Procedures (QSP 7.5), suppliers are to be re-evaluated every two years. The evaluation criteria includes elements such Product Quality (evaluated through non-conforming product) and corrective action responses. These re-evaluations do not provide evidence that the quality system elements are being considered during this process. For example, the re-evaluation form for **(b)(4)**, a critical supplier states "No NCM's have been issued." Your non-conforming product logs shows 6 instances of NCMs since the last evaluation.

c. Your firm does not have evidence of review or acceptance of validated processes used by critical suppliers to manufacture components for your fluid management device. For example, **(b)(4)** provides the electronic control boards which undergo processes such as pick and place, reflow and wave soldering.

5. Failure to have complete risk analysis, as required by 21 CFR 820.30(g).

Specifically, your risk analyses for your fluid management system does not include all hazards or those identified through post market data. For example, complaint numbers 13-0067, 14-0021 and 14-0057 are reports of cartridges leaking. This hazard is not identified in your risk management documents.

Also, your risk estimation/acceptability determination is based on a scale of 1-10 for both severity level and likelihood of occurrence. You have not defined values of 2, 4, 6, 7 or 9 for these variables.

6. Failure to confirm through design verification that design output meets design input requirements, as required by 21 CFR 820.30(f). Specifically,

a. Your functional specification for warming fluids in the fluid management system is the ability to warm fluid from 15.5 degrees C to 40 degrees C. You did not document the temperature at which the fluids were tested, which may influence the results.

b. You did not test Sorbatol (listed as a compatible fluid in the operators manual) to ascertain whether it meets the temperature change requirement listed above.

c. Your requirement for noise of the system was less than 45db at 6 feet. Testing showed levels of 60-70db.

Our inspection also revealed that your firm's Fluid Management System P4000 product is 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 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

Failure to submit a written report to FDA of any correction or removal of a device within 10-working days of initiating such correction or removal, as required by 21 CFR 806.10. For example, from April 2010 to October 2013, your firm made 21 software upgrades since the release of the fluid management system. The software upgrades included fixes for identified hazards such as incorrect fluid deficit calculation issues. Of the 21 software upgrades, 17 were not evaluated for potential

corrections and removals. Your firm implemented all of these software upgrades to all field systems. From April 2011 to April 2014, your firm released at least six software updates to your fluid management system to reduce or eliminate the likelihood of fluid measurement deficiencies. Your firm did not submit a written report to FDA of the correction and removal as required by 21 CFR 806.

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 (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. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Mark E. Parmon, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237. Refer to the WL-15-448762-14 when replying. If you have any questions about the contents of this letter, please contact Mr. Parmon by phone at (513) 679-2700, Ext. 2162; by fax at (513) 679-2773; or by email at mark.parmon@fda.hhs.gov.

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/
Douglas T. Heitkemper, Ph.D.
Acting District Director

More in Compliance Actions and Activities

- Warning Letters
- 2015
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- Tobacco Retailer Warning Letters

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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