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

Merge Healthcare, Inc. 9/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 334-4100
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September 30, 2015

WARNING LETTER

Via UPS Overnight Delivery

Refer to MIN 15 – 17

Justin C. Dearborn
Chief Executive Officer
Merge Healthcare, Inc.
350 N. Orleans Street, 1st Floor
Chicago, Illinois 60654

Dear Mr. Dearborn:

During an inspection of your firm located at 900 Walnut Ridge Drive, Hartland, Wisconsin, on June 3 through July 27, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures software used in clinical settings to manage patient data, including but not limited to Picture Archiving and Communications Systems (PACS) for medical images and Patient Data Modules (PDM) for use in monitoring and recording patient vital signs during cardiac catheterization procedures. 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.

We received your firm's response to the Form FDA 483 (FDA 483) dated August 12, 2015, and our evaluation is discussed below. Violations revealed during the inspection include, but are not limited to, the following:

Quality System

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 (21 CFR), Part 820.

1. Failure to review and evaluate complaints involving the possible failure of a device and labeling to meet any of its specifications, as required by 21 CFR 820.198(c). For example:

A. SF Case #01182363
B. SF Case #01360153
C. SF Case #01410717
D. SF Case #01257221
E. SF Case #01435382

We have reviewed your response dated August 12, 2015. We acknowledge your commitment to updating your complaint handling procedure. However, your response is inadequate in that you have not provided an updated procedure for review. Additionally, you do not include a commitment to perform a retrospective review of quality data sources to determine whether additional complaints have not been appropriately documented within your complaint handling system.

2. Failure to adequately establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, SOP QS-26 (Rev. 7.0, entitled "Complaint Handling"), fails to identify or assign responsibility to any formally designated unit to ensure that complaints are received, reviewed, and evaluated in a uniform and timely manner for the need to correct deficiencies and prevent recurrences of any and all reported device complaints.

We have reviewed your response dated August 12, 2015. Your response is inadequate in that you have not provided an updated procedure for review, including the changes to incorporate a Designated Complaint Handling Unit (DCHU). Additionally, you have not included a timeframe for implementing your new procedure and/or training to include your DCHU.

3. Failure to adequately establish procedures for design validation, as required by 21 CFR 820.30(g). Specifically, QS-57532 (Rev. 2.0, "WI-Customer Validation Process") allows for devices that have not yet fully completed design validation, including software validation, to be shipped to end users for clinical use on patients in a "Limited Availability" basis for the purpose of collecting additional feedback prior to the completion of design validation activities. Further, the Merge HEMO V10.0 was shipped to **(b)(4)** end users for clinical use in cardiac catheterization procedure labs as part of the firm's design validation plan as a "Limited Availability" release; these devices had not been fully validated. Additionally, document number HEMO-6830 (Rev. 1.0, "Customer Validation Plan Merge Hemo 10.0) describes the customer validation process conducted at the two

end user facilities during the “Pre-Release/Limited Availability” release timelines where it is indicated the software will be used in a “production environment,” i.e. for patient use.

We have reviewed your response dated August 12, 2015. We acknowledge your commitment to updating your design validation procedure. However, your response is inadequate in that you have not provided an updated procedure for review, nor have you provided a timeframe for implementation of your new design validation process. It is also unclear whether other in-progress design projects may be affected by your elimination of the “Limited Availability” release, including whether any of your devices are currently being utilized by end users prior to completion of design validation.

4. Failure to document the design review results, including the date, in the design history file, as required by 21 CFR 820.30(e). Specifically, QS-2044 (Rev. 1.0, “WI-Design Review”) describes the process and requirements for conducting design reviews. Design reviews were not performed and/or documented for the Merge Hemodynamics (HEMO) V10.0 design project as required in the work instruction or the design plan as documented in the firm’s Product Development Deliverables Form (PDDF) (QS-1359, Rev. 4.0 and 5.0). The PDDF exists in two releases, one for design transfer of the V10.0 Limited Availability device and a second for the design transfer of V10.0 General Availability device. Both PDDF records require a design review during the “Construction Phase.” Documents HEMO-6628 (Rev. 1) and HEMO-6628 (Rev. 2) document design reviews were conducted; however, the records fail to indicate the date or dates the design reviews were conducted and fail to indicate the results of the design reviews as required in the work instruction. There were no documented design review records indicating that the “Limited Availability” or the “General Availability” versions of the Merge HEMO V10.0 device were transferred to production. Further, section 5.3 of WI-Design Review requires a “**(b)(4)** Review” when the design changes. There were no less than **(b)(4)** design change requests implemented after the “Limited Availability” and “General Availability” release versions of Merge HEMO V10.0. However, there were no records of any design reviews having been conducted after the design changes were implemented or transferred to production.

We have reviewed your response dated August 12, 2015. We acknowledge your commitment to updating you design review procedure. However, your response is inadequate in that you have not provided an updated procedure for review. Additionally, you do not include a plan to review completed design projects to identify any design changes implemented without documented design reviews; your review should include assurance that any problems identified as a result of design changes have been appropriately resolved and that design changes have been verified and/or validated.

5. You failed to adequately establish procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). Specifically, SOP QS-2024 (Rev. 6.0, “Nonconforming Products or Equipment”) fails to require any documented evaluation and/or investigation from the vendors or suppliers of non-conforming materials. The procedure also fails to include a requirement to document any re-work that may have been performed on components or the finished device in the DHR. NCMR #QS-73259 identifies **(b)(4)** circuit boards (Part Number **(b)(4)**) as non-conforming **(b)(4)**. The non-conforming circuit boards were returned to the supplier, re-worked, and returned to the manufacturer where they were re-inspected, accepted, and returned to stock. There was no documented request to the supplier for investigation related to the non-conforming circuit boards. Further, the re-worked circuit boards are uniquely identified by

serial number; however, the re-worked circuit boards were used in the manufacture of the Merge Hemodynamics devices without any documentation of the serial numbers in the respective DHRs.

We have reviewed your response dated August 12, 2015. We acknowledge your commitment to updating your non-conforming products and equipment procedure. However, your response is inadequate in that you have not provided an updated procedure for review. Additionally, you indicate employee training assignments have been issued; however, you do not include training records to demonstrate employees identified as responsible for documenting re-work have been re-trained on the updated procedure.

Correction and Removal

Our inspection also revealed that your Merge Hemo 9.10, 9.20.0, 9.20.1, 9.20.2, 9.30, 9.40.0, 9.40.1, 9.40.2 with Massimo PHASEIN End Tidal CO2 (EtCO2) module 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, as required under section 519 of the Act, 21 U.S.C. § 360(i), and 21 CFR Part 806 – Medical Devices: Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

6. Failure to submit a written report of a correction or removal of a device initiated to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health, as required by 21 CFR 806.10. Specifically, two recall notices (1/21/15 and 4/16/15) were sent to the firm's Install Base having Merge Hemo devices equipped with Phasein EtCO2 modules to explain that the Client PC could "Freeze Up" or record multiple short recordings of Invasive BP readings if the user unplugs the Phasein EtCO2 module and re-plugged into the patient data module. The failure mode adversely affects the collection of the Invasive BP measurements required to calculate the Fractional Flow Reserve (FFR) feature as was reported in no less than eight instances with a patient on the table, leading to delay in treatment while "re-booting" the system (causes temporary loss of all patient vital signs monitoring and recording) or when no treatment was performed at all when the clinician chose to stop treatment due to the inability to obtain accurate and reliable Invasive BP readings.

Your firm failed to notify the FDA of the medical device correction or removal, and did not provide the information required by 21 CFR 806.10. Your firm's actions have been reviewed by FDA and determined to meet the definition of a Class II Recall, which also meets the risk to health threshold for a 21 CFR Part 806 report, as specified in 21 CFR 806.10. Therefore, your firm's actions should have been reported to the FDA.

We have reviewed your response dated August 12, 2015. We acknowledge your commitment to updating your medical device incident reporting and field corrective action procedure. However, your response is inadequate in that you have not provided an updated procedure, specifically how you plan to address determination of a risk to health and the need to report a correction or removal to the Agency. Additionally, you have not provided a timeframe and/or the results of your retrospective review to determine whether additional corrections and removals require reporting to the Agency.

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.

Please notify this office in writing within 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 15 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.

(b)(4)

Your firm's response should be sent to Melissa I. Michurski, Compliance Officer, at the address on the letterhead. If you have any questions about the content of this letter please contact Ms. Michurski at (612) 758-7185.

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, form 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/
Michael Dutcher, DVM
Director
Minneapolis District

xc:
Steven M. Oreskovich
Chief Financial Officer
Merge Healthcare, Inc.
900 Walnut Ridge Drive
Hartland, WI 53029

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)