Inspections, Compliance, Enforcement, and Criminal Investigations

Meridian Medical Systems LLC 7/3/13

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
Telephone: (513) 679-2700
FAX: (513) 679-2761

July 3, 2013

Via United Parcel Service

WARNING LETTER
CIN-13-406958-26

Larry R. Cornell, President
Meridian Medical Systems, LLC
325 Harris Drive
Aurora, OH 44202

Dear Mr. Cornell:

During an inspection of your firm located in Aurora, OH on May 13 through May 31, 2013, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures x-ray systems. 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.

These violations include, but are not limited to, the following:

1. Failure to establish a design history file, as required by 21 CFR 820.30(j). Specifically,

Your firm does not have a design history file (DHF) for the Meridian DR 200 single panel X-ray system. The system is comprised of a workstation, flat panel detectors, acquisition software and X-ray hardware. Missing elements of the DHF include:

- A design plan for the project
- Established or approved design inputs/outputs for the system
- Verification or Validation testing for the system
- Design Transfer
- Risk Management for the system
- Design Reviews.

2. Failure to adequately establish procedures for corrective and preventive actions, as required by 21 CFR 820.100(a). Specifically,

Your firm does not have a method to obtain information from quality data sources such as complaints, servicing or installation of your X-ray systems. Nearly all of these activities are performed by your distributers who have provided no quality data records and have no contractual obligation to provide this information to you. Corrective/preventive actions cannot be taken by your firm without this type of quality data.

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

Your Purchasing Process and Supplier Evaluation Process Map (7.4.1) is ambiguous on how you will monitor your suppliers. Your process map lists the "input" for monitoring trends of performance as identifying performance parameters for suppliers. These parameters are not defined. Additionally, your firm has no quality data records to show that suppliers are being monitored.

4. Failure to document the evaluation of potential suppliers, as required by 21 CFR 820.50(a)(1). Specifically,

You have no records to show how any of your suppliers were qualified. Your Purchasing Process and Supplier Evaluation Process Map (7.4.1) shows the evaluation of suppliers by capability survey, trial order and past performance. Your firm has no documentation of performing any of these activities. Also, your firm has not inquired, reviewed or approved any validated processes associated with the manufacturing of components/accessories by your suppliers.

5. Failure to establish procedures for device history records to ensure that DHR's for each unit are maintained to demonstrate that the device is manufactured in accordance with 21 CFR 820, as required by 21 CFR 820.184. Specifically,

Your firm does not have procedures to describe the content of your Device History Records (DHR's). In addition, eleven of eleven DHR files reviewed showed that all were incomplete as the only record in the files was your testing of the flat panel detectors, which is only one part of the X-ray system. The DHRs do not include installation records; records of any non-conformities; records regarding the X-ray hardware, workstation or acquisition software; or records of final product testing and quality release of your systems.

6. Failure to establish procedures for finished device acceptance to ensure that each production lot of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). Specifically,

There are no procedures for final product testing and quality release of your systems.

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 to develop, maintain, and implement written procedures for Medical Device Reporting, per 21 CFR 803.17. Specifically, your firm has not developed procedures for medical device reporting (MDR).

We received a response from you, dated June 17, 2013, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm. The adequacy of your response cannot be determined at this time as it lacks sufficient details of how you plan to correct the listed deficiencies.

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 (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 Mr. Mark E. Parmon, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237. Refer to the CIN-13-406958-26 when replying. If you have any questions about the contents of this letter, please contact: Mr. Parmon at (513) 679-2700, Ext. 2162, or by facsimile at (513) 679-2773.

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/
Paul J. Teitell
District Director
Cincinnati District

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Note: If you need help accessing information in different file formats, see Instructions for