



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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August 8, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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Mr. John R. Speer
President
Medical Instruments Technology, Inc.
385 North 3050 East
St. George, Utah 84790

Ref. #: DEN-01-45

Dear Mr. Speer:

On April 16 through 24, 2001, Investigator Ricki A. Chase-Off of our office conducted an inspection of your establishment in St. George, Utah. Our investigator determined that your firm reprocesses various single use devices such as electrophysiology ablation catheters, diagnostic cardiac catheters, laproscopic instruments, guidewires, orthopedic devices and compression catheters. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Failure to validate a process with a high degree of assurance and have that process approved and documented according to established procedures, as required by 21 CFR 820.75(a). For example:
 - a. MIT's bioburden and total organic carbon validation protocols are inadequate in that you do not specify which catheters (i.e., brand and model) were used in the validation studies.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. More importantly, there is no justification to demonstrate that the representative catheters chosen for the bioburden validation will sufficiently provide worst case sterilization for the ~~XXXX~~ for which MIT is applying for ~~XXXXXXXXXX~~.

There is no comparison data to show that the fixed curve catheters are equivalent to the ~~XXXX~~ and that the sterilization requirements are equivalent. MIT also failed to submit the validation procedures.

- b. MIT's validation of the ~~XXXX~~ impedance, resistance, and continuity testing is inadequate in that it was conducted using a system whose validation documentation is absent and cannot be verified as adequate.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. MIT did not submit a copy of procedure ~~XXXX~~. Further, no justification was submitted to demonstrate that the change to a manual system is adequate. No evidence was submitted that installation qualifications were performed on the test equipment. Also, the second party review was not identified nor was that person's credentials indicated or apparently reviewed under the requirements of 21 CFR 820.75(b)(1).

- c. The validation of the heat sealer is inadequate in that only one bag type was used in the validation; however, MIT seals two different bag types in ~~XXXX~~ production. There was no evaluation of the different bag types or the difficulty in sealing the different bag types of the selection of one bag type over another as the "worst case" choice.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. Further, MIT did not submit a copy of the documentation and procedure ~~XXXX~~.

- d. The parameters of the sterilization validation study performed by the contractor for the ~~XX~~ ~~XXXX~~ sterilization equipment were not identified by MIT, nor was the contractor's validation protocol reviewed by MIT.
- e. Commissioning and performance qualifications for the ~~XX~~ equipment were not adequately validated in that temperatures for half cycle and full cycle loads for preconditioning and sterilizing were not correctly established. The AAMI 11135-1994 "Medical Devices -- Validation and Routine Controls of Ethylene Oxide Sterilization" American National Standard utilized by the contractor, ~~XXXXXXXXXX~~, was incorrectly referenced.
- f. MIT does not have a procedure or a validation for the reesterilization of a failed load when the failure is the result of positive biological indicators.

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- g. MIT does not investigate the root cause of failed sterilization loads or positive biological indicators.
- h. MIT failed to document the selection and design specification of the ~~XXXXX~~ catheter testing equipment, including the computer system, software, data acquisition hardware, and meters.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the documentation and the changed procedure.

- 2. Failure to review and evaluate the process and perform revalidation when changes or process deviations occur, as required by 21 CFR 820.75(c). For example, MIT failed to document the verification, validation, or reason for not revalidating the RO water system after, to the system.

Your response of May 4, 2001, is inadequate because the validation of the water system has not been initiated and the documentation and the procedure has not been submitted.

- 3. Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation by identifying the different groups that provide input into the design process, as required by 21 CFR 820.30(b). For example:
 - a. The design plan does not identify and describe interfaces among the groups participating in the design process.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the documentation and the changed procedure.

- b. The design plan has not been reviewed and approved by ~~XXXXXXXXXX~~ as set forth in the procedures.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure.

- 4. Failure to establish and maintain design input procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, as required by 21 CFR 820.30(c). For example:
 - a. MIT failed to specifically identify and evaluate sterilization in the design process.

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Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure.

- b. MIT failed to specifically identify and evaluate labeling and package inserts in the design process.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure.

- c. MIT failed to specifically identify and evaluate the selection of the cleaning chemicals used in the decontamination procedure.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure.

- 5. Failure to establish and maintain design review procedures to ensure that formal documented reviews are planned and conducted at appropriate stages in the design development and that the results of the review and the individuals performing the review are documented in the design history file, as required by 21 CFR 820.30(e). For example:

- a. MIT failed to identify the members of the Design Review Committee.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. MIT did not submit a copy of the changed procedure. Further, the documentation identifying the members of the Design Review Committee was not provided.

- b. Meetings of the Design Review Committee and the review process were not documented.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure.

- 6. Failure to establish and maintain procedures to verify the device's design, as required by 21 CFR 820.30(f). For example, verification activities were not documented or reviewed.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure or the documentation of the verification activities.

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7. Failure to establish and maintain procedures to validate the device's design, as required by 21 CFR 820.30(g). For example, design validation, including identification of the design, methods, dates, and individuals performing design validation were not documented for packaging, labeling, receiving, or distribution.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of either the documentation or the procedure for each device.

8. Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h). For example, design transfer activities were not defined or documented.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the procedure.

9. Failure to establish and maintain a Device History File for each type of device, as required by 21 CFR 820.30(j). For example, the design history file was incomplete in that necessary records were either not contained within or made reference to in the design history file. Documentation was maintained in various locations and was not documented as being part of the design process.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and you did not submit a copy of the changed procedure or the documentation of the implementation of these changes.

10. Failure to assure that corrective and preventive activities are established and maintained, and that those activities and the results are documented, as required by 21 CFR 820.100(b). For example, MIT failed to document corrective and preventive action for two consumer complaints.

Your response of May 4, 2001, is inadequate because you did not submit a copy of ~~XXXXXXXXXX~~ and a copy of the corrective and preventive procedure indicating these activities will be adequately performed in the future.

11. Failure to establish and maintain adequate procedures for implementing corrective and preventive actions that employ appropriate analytical and statistical methodology, as required by 21 CFR 820.100(a)(1). For example:

- a. Complaints are not evaluated for specific devices. Complaints are grouped for laparoscopic instruments but do not examine the brand or model of instrument.

- b. Nonconformances are not evaluated as to the specific nonconformance. An equipment nonconformance does not identify if the equipment was out of specification, out of calibration, or needed maintenance.
- c. The statistical analysis does not capture all sources of quality data. Rework activities and document and process changes are not captured and evaluated.

Your response of May 4, 2001, is inadequate because procedure ~~XXXXXX~~ documenting the above corrections was not submitted.

- 12. Failure to establish and maintain corrective and preventive action and to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, complaint evaluation does not examine the relationship between the type of complaint and the type of device. Complaints are grouped as instrument failure but do not identify or evaluate which specific device failed.

Your response of May 4, 2001, is inadequate because procedures ~~XXXXXX~~ and ~~XXXXXX~~ documenting the above corrections were not submitted.

- 13. Failure to review and evaluate all complaints to determine if an investigation is necessary and to document the results of that decision, as required by 21 CFR 820.198(b). For example, MIT failed to document MDR reviews and the decisions for the complaints.

Your response of May 4, 2001, is inadequate because MIT did not submit a copy of the corrected MDR form, nor a copy of the procedure documenting the corrective action.

- 14. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example:

- a. MIT states in procedures that it used ~~XXXXXX~~ for drying decontaminated and cleaned devices, but failed to document verification or validation of the ~~XXXXXX~~ ~~XXXXXX~~ to demonstrate that it meets the specification of ~~XXXXXX~~

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and MIT has not established a procedure to verify the adequacy of the ~~XXXXXX~~ and has not ceased using the current ~~XXXXXX~~.

- b. MIT does not maintain control of the processing activities in that clients are told to decontaminate product prior to sending it to them for reprocessing, but are not told which disinfectant must be used and are not told not to use ~~XX~~ which can damage the devices.

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Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. MIT has not provided a copy of procedure ~~XXXX~~, and has not provided a copy of the correspondence sent to customers advising them of the revised procedures.

15. Failure to establish and maintain procedures for changes to a specification, method process, or procedure; such changes shall be verified or validated before implementation of the changes and documented, as required by 21 CFR 820.70(b). For example, the system allows data to be changed by the technician and tests to be repeated without leaving a document trail and without validation for reprocessing up to ten times.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. MIT has not provided a copy of procedure ~~XXXX~~. MIT has not identified the authorized signatory, qualifications of the authorizing personnel, or the qualifications of an authorized person. No validation was provided that reprocessing can be performed ~~XXX~~ times.

16. Failure to validate computer software for its intended use according to an established protocol prior to approval and issuance, and document the results of these validation activities, as required by 21 CFR 820.70(i). For example:

- a. MIT failed to provide documentation of the validation of the computer system used to test ~~XXXX~~ performance in QC Processing for impedance, resistance, and continuity for: (1) computer hardware, ~~XXXXXX~~, ~~XXXX~~, and ~~XXXX~~ software; (2) data acquisition hardware; and (3) impedance, high resistance, and continuity meters.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, MIT did not submit a copy of procedure ~~XXXXXX~~. No verification and/or validation was submitted to demonstrate that the change to a manual system is adequate.

- b. The validation of the computerized label generating system, ~~XXXX~~ software with ~~XXXX~~ printer, is inadequate in that it failed to identify the specific software and hardware that the validation covered.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. No copy of the labeling was provided and no validation was provided to indicate the accuracy and reliability of the system.

- c. MIT failed to document the selection and design specification of the QC Processing ~~XXXX~~ testing equipment, including the computer system, software, data acquisition hardware, and meters.

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Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001, and the documentation was not submitted.

17. Failure to establish and maintain finished device acceptance procedures to assure that finished devices meet acceptance criteria, as required by 21 CFR 820.80(d). For example, MIT failed to adequately conduct a quality review of the device history records in that incomplete and incorrect records were approved by the quality assurance technician. Records which were missing reason descriptions for nonconformances and records which contained unapproved changes were approved by Quality Assurance.

Your response of May 4, 2001, is inadequate because: (1) training needs and procedures were not identified; (2) the training procedure was not submitted; (3) a copy of completed training was not provided; and (4) the qualification of the training instructor was not established and documented.

18. Failure to establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups, as required by 21 CFR 820.60. For example, MIT does not have written procedures which describe how the devices are to be identified to ensure that they are not processed more than ~~XX~~ times, the limit set by MIT.

Your response of May 4, 2001, is inadequate because there is no justification why the corrections will not be implemented until August 14, 2001. There was no documentation submitted to describe how the serial number of each ~~XXXX~~ will be generated, identified, recorded, and controlled. Further, there was no validation and justification provided for reprocessing the ~~XXXXXX~~ times.

19. Failure to maintain device master records (DMRs) as required by 21 CFR 820.181. For example, the device master record (DMR) is incomplete in that it does not contain the following items, or describe them where the following items are located as part of the DMR:
- Device specifications including appropriate drawings, composition, formulations, and component specifications
 - Production process specifications including equipment, methods, and all procedures and environmental considerations
 - Quality assurance procedures, specifications, acceptance criteria, and QA equipment to be used
 - Packaging specifications including methods and processes
 - Installation, maintenance, and servicing procedures and methods

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Your response of May 4, 2001, is inadequate because procedure ~~XXXXXX~~ was not submitted demonstrating the changes.

20. Failure to maintain device history records (DHR) to assure that each batch, lot, or unit is manufactured in accordance with the DMR, as required by 21 CFR 820.184. For example, the DHR is incomplete in that it does not contain the following:
- Label and labeling used in the manufacture of the specific devices
 - Test data and acceptance records
 - Procedures used in the manufacturing process

Your response of May 4, 2001, is inadequate because the DHR procedure was not submitted demonstrating the changes.

21. Failure to establish and maintain procedures to control all documents, as required by 21 CFR 820.40. For example:
- An older, unapproved version of a procedure was discovered in research and development.
 - Master documents are not under the sole control of Quality Assurance to which they are designated and they are stored on unsecured computers with access allowable to unapproved personnel.

Your response of May 4, 2001, is inadequate because: (1) no procedure was developed and submitted to control obsolete documents; (2) no documentation was submitted demonstrating that training of personnel was performed; and, (3) no copy of the changed training procedure incorporating this corrective action was provided.

- Failure to follow change control procedures in that changes were made to work orders, including product model number and quantity, without the change being reviewed or approved.

Your response of May 4, 2001, is inadequate because no documentation was submitted demonstrating that training of personnel was performed and no copy of either the change control procedure or training procedure incorporating this corrective action was provided.

22. Failure of management with executive responsibility to effectively establish and maintain quality system requirements, as required by 21 CFR 820.20(b)(3)(i). For example:
- Design controls were not fully developed, reviewed, or approved by management.
 - Decontamination residue, packaging selection, labeling design, and design review meetings were not documented.

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- b. The audit of the Quality assurance department failed to document deviations in the Quality Assurance policies and the errors not discovered by the Quality Assurance personnel.

Your response of May 4, 2001, is inadequate because the audit procedure was not provided.

- 26. Failure to establish and maintain the requirements that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example, MIT hired a consultant to design and evaluate the system used in QC Processing for testing the impedance, resistance, and continuity of ~~XXXXXX~~; however, you failed to:

- a. Establish and maintain requirements to be met by the consultant.
- b. Document the evaluation of the consultant's ability to meet any quality requirements or the specific needs of MIT.

Your response of May 4, 2001, is inadequate because no procedure was submitted establishing the requirements for a consultant and no documentation was provided that evaluated and approved the selection of the consultant.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by us without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

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Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,


Thomas A. Allison
District Director