



DEPARTMENT OF HEALTH & HUMAN SERVICES

94577d
Public Health Service

Food and Drug Administration
Detroit District
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 23, 2004

WARNING LETTER
2004 - DT - 04

Mr. James D. Maatman
President
Michigan Instruments, Inc.
4717 Talon Court, S.E.
Grand Rapids, MI 49512-5408

Dear Mr. Maatman:

Investigators George G. Calafactor and Anthony R. Petriella conducted an inspection of your firm dated November 4 – December 9, 2003. At the conclusion of that inspection, the investigators issued to you a FORM FDA-483, list of Inspectional Observations, (copy attached).

The inspection covered your product, the Thumper Model 1007 Mechanical CPR System, that is a medical device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act)(see also Title 21, Code of Federal Regulations (CFR), section 870.5200).

Our inspection found that your firm is operating in violation of the Quality System Regulation (QSR), Title 21 CFR Part 820, rendering your devices 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 compliance with the QSR.

The FORM FDA-483 describes, among others, the following deviations from the QSR:

QUALITY AUDITS – 21 CFR 820.22

1. You failed to establish procedures for quality audits to be conducted by individuals who do not have direct responsibility for the matters being audited (FDA-483 #3) as required by 21 CFR 820.22.

DESIGN CONTROLS – 21 CFR 820.30

2. Your Design Control procedure, SOP [REDACTED], Section 9, fails to include all the elements necessary to control the design of the device to ensure that specified design requirements are met (**FDA-483 #6.A**) as required by 21 CFR 820.30(a).

3. You failed to establish and maintain design and development plans for eight of nine design change projects (**FDA-483 #6.B.i**) as required by 21 CFR 820.30(b).

4. You failed to address the basic elements of design and development planning, to include inputs and outputs, verification or validation, design reviews, and design transfer in your design plan for the [REDACTED] Development Plan okayed on 28-Aug-03, (**FDA-483 #6.B.ii**) as required by 21 CFR 820.30(b).

For example, Change Authorization Form (CAF) # 13727 dated 25-Aug-03, describes and documents implementation of this change to use a [REDACTED] on the piston and a different lubricant.

Upon implementation of that change, leakage of the pressurized compression gas resulted in "perhaps 1 in 5" units, leading to CAPA # [REDACTED], to investigate the cause of the leaking. The subsequent Change Authorization Form # 13768, approved on Oct. 30, 2003 provides for the machining of a variable depth groove in the piston depending on the currently available size of the [REDACTED]. This change is one of the eight examples cited under number 3 above as lacking any Design and Development Plan.

5. You failed to establish and maintain your Design History Files (DHF) for nine design change projects in that they fail to include documentation of the design steps performed (**FDA-483 #6.C.**) as required by 21 CFR 820.30(j).

PRODUCTION & PROCESS CONTROLS – 21 CFR 820.70

6. You have failed to establish and follow procedures to monitor and control production processes (**FDA-483 # 16**) as required by 21 CFR 820.70(a)(2). For example, the 95 specifications listed in the "unapproved" computerized Process Control Data and the CNC Program Validation forms for the machining of the [REDACTED] have not been formally established into a monitoring and controlling procedure. This resulted in the failure to fully monitor and control production of three lots of [REDACTED] as listed in the referenced FDA-483 # 16 observation.

7. Your process change procedure SOP [REDACTED], Section 5, fails to address verification or validation of changes (**FDA-483 # 10**) as required by 21 CFR 820.70(b).

8. You failed to perform or document the verification or validation of production process changes, such as the Inspiratory Time Test Specification, [REDACTED] on 12/17/2002 and the [REDACTED] software changes on 11/7/2000 (FDA-483 #11, c. and # 11, i) as required by 21 CFR 820.70(b).

9. You failed to validate the computer software, and all subsequent changes to this software, used in the operation of automated production machinery (FDA-483 # 18), as required by 21 CFR 820.70(i).

CORRECTION AND PREVENTIVE ACTION – 21 CFR 820.100

10. Your Corrective and Preventive Action (CAPA) procedure SOP [REDACTED], Section 15, fails to verify or validate the corrective and preventive action to ensure it does not adversely affect the finished device (FDA-483 # 12) as required by 21 CFR 820.100(a)(4).

RECORDS RETENTION – 21 CFR 820.180

11. You failed to retain records for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer, as required by 21 CFR 820.180(b). Specifically, you failed to retain portions of the Device Master Records, consisting of early versions of computer software, following revisions to that software (FDA-483 # 19).

DEVICE MASTER RECORD – 21 CFR 820.181

12. You failed to maintain Device Master Records. Specifically, some of your Device Master Records (DMR's) do not include or refer to the location of production and process specifications (FDA-483 # 14) as required by 21 CFR 820.181(b). For example, the portion of the DMR "approved" on 4/21/00 for producing the [REDACTED] [REDACTED] on the [REDACTED] machine, lacks any specifications while an "unapproved" computer generated specification sheet lists 95 specifications.

DEVICE HISTORY RECORD – 21 CFR 820.184

13. You have failed to establish and maintain procedures to ensure Device History Records (DHR's) demonstrate the devices are manufactured according to the Device Master Records and the requirements of 21 CFR Part 820, as required by 21 CFR-820.184. Specifically, as listed in (FDA-483 # 15 A.i and A.ii), there are no procedures to ensure:

- a. A review of the DHR to demonstrate the device was made according the DMR.
- b. There are examples of the primary identification label and labeling used on each unit.

COMPLAINT FILES – 21 CFR 820.198

14. You have failed to effectively implement and follow your SOP [REDACTED], Section 21, Customer Contacts/Service Reports. Specifically, the records generated as follow-up to complaint reports and service requests regarding possible device failures do not include an evaluation to determine if the complaints represent events that are required to be reported to FDA as Medical Device Reports (FDA-483 # 8 and 9) as required by 21 CFR 820.198(b) and (c).

SERVICING – 21 CFR 820.200

15. Your established procedure to address device servicing SOP [REDACTED], Section 21, fails to address all the requirements of 21 CFR 820.200 (a)(b) and (c) in that it fails to provide for the following three elements listed in (FDA-483 # 17):

- a. The rationale for differentiating routine from non-routine events.
- b. Conducting additional investigations to determine if MDR reporting is necessary.
- c. The statistical analysis of data to detect recurring quality problems.

STATISTICAL TECHNIQUES – 21 CFR 820.250

16. You failed to establish and maintain procedures to ensure that sampling methods are adequate for their intended use. Specifically, you failed to document the procedures used to ensure the adequacy of the selected sampling plan used in the verification of the computer software used with the [REDACTED] machine (FDA-483 # 20) as required by 21 CFR 820.250(b).

MEASUREMENT & TEST EQUIPMENT – 21 CFR 820.72

17. You failed to ensure that your equipment is routinely calibrated, as required by 21 CFR 820.72(a). Specifically, you failed to implement and follow your established Measurement Equipment Control procedure SOP [REDACTED], Section 8 (FDA-483 # 21).

DEVICE PACKAGING – 21 CFR 820.130

18. You failed to establish procedures to ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution (FDA-483 # 7) as required by 21 CFR 820.130.

The above is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the regulations. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, pending 510(k) or PMA applications and export approval requests may not be approved until the above violations are corrected.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice, such as seizure and/or injunction.

We acknowledge receipt of your January 14, 2004 letter written in response to the FDA-483 wherein you acknowledged your obligation to meet all regulatory requirements, and your intention to complete corrective actions and file a completed response by February 27, 2004.

We also acknowledge your January 26, 2004 letter to inform us that you are working with Mr. Bruce H. Barkalow concerning your regulatory compliance matters and that he has your full authority to represent Michigan Instruments and to discuss these issues with the FDA. Mr. Barkalow communicated directly with the Detroit District office on February 20, 2004 that he is working to address FDA-483 observations 4, 5, 8, and 9. He has provided a February 19, 2004 draft revision of your written procedure, PS181, Section 21, covering Service Requests, Complaints, and Reportable Events. We have reviewed that draft revision and have the following comments:

1. The procedure improves and more clearly addresses the use of the MedWatch form, documentation of the mailing date, and the documentation and record keeping requirements that were listed in **FDA-483 # 4 and 5**. We did not cite those two observations in this warning letter as the original procedure appears to have adequately addressed those issues in a less direct manner.
2. The procedure appears to adequately address the steps to complete the SIR (Service Investigation Report) and the associated SIR Flow Chart. Steps 4 & 5 on pages 6-7 are specific in the instructions to document the rationale for the decisions to conduct an investigation (or NOT to conduct an investigation) of an event and to support a decision that an event is not MDR reportable. **FDA-483 # 8 and 9** listed violations of these requirements as cited above in violation #14 of this warning letter.

However, it is our perception that the blank SIR and Flow Chart forms were designed for check in a box or short answers that are to be entered into the computerized system that provides very limited space for detailed answers. This appears to have caused inappropriate or insufficient detail in entries that failed to fully document the decision making process required to comply with the regulations. You need to make sure your records system provides instructions for and adequate space for entry of complete documentation of the decision process.

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Grand Rapids, MI

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Please notify this office in writing, within fifteen (15) working days of receipt of this letter, as to any additional steps being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely,



Joann M. Givens
District Director
Detroit District

Enclosed: FDA-483