Inspections, Compliance, Enforcement, and Criminal Investigations

Michigan Instruments, Inc. 01-Oct-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
October 1, 2001
WARNING LETTER
2002-DT-01

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

Dear Mr. Maatman:

Investigator Leslie A. Paul conducted an inspection of your firm between January 30 and February 15, 2001 At the conclusion of that inspection, Investigator Paul issued to you a FORM FDA-483, list of Inspectional observations, (copy attached).

First, the deviations from the Medical Device Reporting Regulations (MDR), Title 21, Code of Federal Regulations (CFR), Part 803, are listed as items 1 and 2 on the FDA-483. These deviations caused the ?Thumper" cardiopulmonary resuscitator, to be misbranded within the meaning of section 502(t)(2) [21 U.S.C. 352(t)(2)] of the Federal Food, Drug and Cosmetic Act (the Act).

Second, you replaced the pneumatic timer (oscillator) in the Model 1007 with a Mechanical timer (oscillator to address complaints that the device produced unexpected compression to ventilation ratios. This change to the mechanism that controls chest compressions is a change or modification in the Thumper that could significantly affect the safety or effectiveness of the device. The failure to submit a premarket notification (section 510(k)) submission for this change, as required by 21CFR 807.81(a)(3)(i), causes the Thumper to be misbranded within the meaning of section 502(o) [21 U.S.C. 352(o)] and adulterated within the meaning of section 501 (f)(l)(B) [21 U.S.C. 351(f)(l)(B)] of the Act.

Third, under the Act, your firm is required to submit a written report to FDA within ten working days of initiating either a product correction or removal that is intended to: (1) reduce a risk to health; or (2) remedy a violation of the Act which may present a risk to health. These reports will help FDA protect the public health by improving the agency?s ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

Our records indicate your firm has initiated a removal, as defined in 21 CFR 806.2(i), and has not submitted the required report to your local FDA District Office at:

U.S. Food and Drug Administration
Recall Coordinator
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179

The removal involved replacing the pneumatic timer in Model 1007 devices returned for servicing with a mechanical timer. This change was made to address complaints that the device did not deliver the compression to ventilation ratios given in the labeling.

Because you have not submitted a report of this removal, your product is in violation of the law. In legal

terms the product is misbranded under section 502(t)(2) of the Act for failure to make a report as required by Section 519 of the Act.

Fourth, the deviations from the Quality System Regulation, Complaint Files, 21 CFR 820.198 are listed as items 3 and 4 on the FDA-483. These deviations in the complete documentation of complaint handling caus your medical devices to be adulterated within the meaning of section 501(h) [21 U.S.C. 351(h)] of the Act.

The failure to investigate and document decision-making maybe masking other unreported MDR events. In fact, the two examples identified in item 3 of the FDA 483, [redacted] (device failed while being used on a patient) and [redacted] "blood was coming out of the patients mouth after several strokes") are reportable MDR malfunctions. Both of these events are considered to be reportable MDR malfunctions since the firm is in receipt of information that reasonably suggests a reportable event occurred and ?does not have documentation that justifies a decision not to submit an MDR report.

FDA recognizes that firms can experience difficulties in obtaining information that is missing from complaint reports. However, it is important to recognize that the MDR regulation places the responsibility for complete reporting of information on the device manufacturer. FDA expects firms to make its business partners awar of its reporting responsibilities. Refer to 21 CFR 803.50(b)(2) - "Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, distributors and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information."

We acknowledge receipt of your March 1, 2001 letter written in response to the FDA-483, and have the following comments:

1. FDA-483 point #l reports the failure to file MDR (Medical Device Reporting) Reports for events described in complaint reports, [redacted] and [redacted] The events described in these reports are malfunctions that you are required to report to FDA. CM position on this matter, explained to you in a letter dated June 10, 1997, from Brenda J. Holman, the Detroit District Director at the time, has not changed. It is as follows, Th failure of a device while used on a patient that subsequently dies represents a situation in which the device may have caused or contributed to the death and the event requires an MDR death report. An exception exists when the health care professional is able to state that the device was not a factor in the death, in which case the event should be reported as an MDR malfunction.

2. Your response to FDA483 point #6 regarding 21 CFR Part 11- Electronic Records is not adequate as explained in more detail below.

3. Your responses to points 3 and 4 of the FDA-483 points indicate you have already taken appropriate steps to resolve those issues. We will evaluate the results of those changes in a future inspection.

4. Your response to point 5 of the FDA-483, documenting that the training of the indicated employee had occurred in January 1999, and was repeated in February 2001 for all affected employees, is satisfactory.

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 fake 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.21 CFR Part 11

During the FDA inspection it was discovered that electronic records are used to establish the firm?s Complaint Files, 21 CFR 820.198. However there is no documentation to establish that these electronic records meet the requirements of 21 CFR Part 11, Electronic Records; Electronic Signatures. The requirements of 21 CFR Part 11 are designed to ensure that electronic records are trustworthy, reliable, and generally equivalent to paper records.

For example, review of your electronic complaint files reveals they have not been properly validated, there is no ability to generate accurate and complete copies of records in human readable and electronic form, there is no protection of records to enable their accurate and ready retrieval, access to your system has not been limited, as well as other significant deficiencies.

We strongly encourage you to perform a thorough and complete evaluation of all your electronic records in accordance with 21 CFR Part 11 as well as any guidance generated by FDA to assure conformance to our

requirements. Do not limit your evaluation solely to the examples cited above. Only electronic records and electronic signatures that meet 21 CFR Part 11 may be used to satisfy the requirements of 21 CFR 820.198 Complaint Files.

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 tim 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

Page Last Updated: 08/14/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.