



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94342d
Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

October 9, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 01

Philip W. Jones
President
MedPACS Displays, Inc.
1020 James Drive, Suite H
Hartland, Wisconsin 53029

Dear Mr. Jones:

During an inspection of your establishment located in Hartland, WI, on September 10-12, 2003, our investigator determined that your establishment manufactures WinPACS Display Systems which 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 regulation for medical devices, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows:

1. Procedures to control the design process of a device were not complete, which is required by 21 CFR 820.30(a). Specifically, your Product Design Procedure, OP-015, does not address issues such as risk analysis [21 CFR 820.30(g)], ensuring that design outputs meet design input requirements [21 CFR 820.30(f)], and ensuring that incomplete, ambiguous, or conflicting requirements of the design inputs are addressed [21 CFR 820.30(c)].
2. The design history file for your WinPACS WebDisplay device does not demonstrate that the design was developed following the design control

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requirements of 21 CFR 820.30(j). Specifically, the WebDisplay design history file does not contain documentation of design verification [21 CFR 820.30(f)], design validation [21 CFR 820.30(g)], design outputs [21 CFR 820.30(d)], design reviews [21 CFR 820.30(e)], and risk analysis [21 CFR 820.30(g)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and 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 FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We have received your letter dated September 21, 2003, which replied to the FDA-483 issued on September 12, 2003. The corrective actions that you have reported for observations #4 and 5 appear to be adequate if they are fully implemented in a timely manner. Observation #3 was corrected and verified during the inspection. Your letter stated that corrective action is ongoing for observations #1 and 2 but you did not provide any details about the nature of those corrective actions.

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 pre-market submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

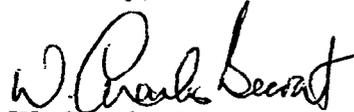
Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your response should be sent to Compliance Officer Timothy G. Philips at the address indicated on the letterhead. If you have any questions concerning this matter, please contact Mr. Philips at (612) 758-7133.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TGP/ccl

