



**WARNING LETTER**  
**VIA EXPRESS MAIL**

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

JAN 12 2001

Michael Brock  
President  
Danplex A/S  
Sanderumvej 130  
DK-520 Odense SV  
Denmark

Dear Mr. Brock:

We are writing to you because on September 11-15, 2000, an investigator from the Food and Drug Administration (FDA) along with an auditor of the Danish Medical Devices Certification, European Conformity Assessment Bodies, collected information that revealed serious regulatory problems involving the audiological products, such as the diagnostic audiometers, which are made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of 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, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21 Code of Federal Regulations (CFR), Part 820, as follows:

1. Quality audits were not conducted as prescribed by internal procedures to verify that all elements of the quality system are effective in fulfilling the firm's quality objectives as required by 21 CFR 820.22. Specifically, design controls were not covered in any internal audit for at least 2 years.

Your proposed corrective action appears inadequate. Your corrective action cover letter stated, "Internal audit of design planed". It is unclear if your firm is going to conduct an audit of a specific device design or the entire design control operations. Secondly, your corrective action could not be verified since the internal audit schedule was provided in a foreign language.

2. Procedures for conducting quality audits were not completely established, as required by 21 CFR 820.22. Specifically, the procedure [REDACTED] does not clearly prescribe re-audit, where necessary, and according to [REDACTED] re-audits are not generally performed until the next planned audit of the problem area.

The procedural change you have implemented that allows [REDACTED]

[REDACTED] appears adequate.

3. The design history file for the DA65 audiometer does not demonstrate that the design was developed according to the approved design plan, as required by 21 CFR 820.30(j). Specifically, (a) 16 DA65 devices were distributed via [REDACTED] before their design was "formally" approved [REDACTED]; (b) no risk summary for the design outputs of [REDACTED] as required in the project plan; (c) a design review was not performed at the end of all of the described phases.

The corrective action appears inadequate since you do not describe how you plan to prevent the problem from recurring. Your corrective action only identifies how the specific deviations for the [REDACTED] design plan were resolved. Additionally, we could not verify the proposed correction since the supporting documents were in a foreign language.

4. During design verification, you did not confirm that design outputs meet the design inputs requirements, as required by 21 CFR 820.30(f). As noted on the form FDA-483, unresolved discrepancies were observed at the completion of the design verification. For instance, in document [REDACTED] the conclusion under [REDACTED] "There is no general conclusion of the testing was satisfactory for approval. Secondly in the risk analysis [REDACTED]". The design verification conclusion did not address this comment. [REDACTED]

As noted earlier, verification of your firm's corrective action plan cannot be determined since the supporting documentation was in a foreign language. Secondly, you do not describe the actions taken to prevent this deviation from recurring. You only identified how the [REDACTED] and that [REDACTED]

5. Procedures to control the design process of the device were not complete. Specifically, no requirement for a risk analysis is found in the design control, as required by 21 CFR 820.30(g).

Please provide the English translation of your corrective action in order to verify that risk analysis is now referenced in the procedures to control design process.

6. Failure to adequately control documents as required by 21 CFR 820.40. During the inspection, documents that were not approved were observed at a location where they were used. Specifically, in the device master record for the [REDACTED] specifications were not formally approved. Documents such as [REDACTED] specifications shall be reviewed and approved by designated individuals.

This deviation was corrected during the inspection and provided to the investigator.

7. Changes in methods and procedures needed to correct and prevent identified quality problems are not always implemented, as required by 21 CFR 820.100(a)(5). Specifically, in relation to complaint report [REDACTED] was not implemented.

The proposed corrective action is inadequate. The English translation is needed to ensure measures have been taken to prevent this problem from recurring.

8. The corrective and preventive procedures addressing the analysis of sources of quality data to identify existing and potential causes of non-conforming products or other quality problems were not completed, as required by 21 CFR 820.100(a)(1).

This deviation was corrected during the inspection and the documentation was provided to the investigator.

9. Complaint handling procedures were not complete to ensure that all complaints that are required pursuant to MDR requirements, as required by 21 CFR 820.198(a)(3).

This deviation was corrected during the inspection and the documentation was provided to the investigator.

10. Complaints involving the possible failure of a device to meet any of its specifications were not investigated to determine the root cause of the failure, as required by 21 CFR 820.100(a)(2). Specifically, complaint report [REDACTED] do not contain the root cause.

The corrective action is inadequate since your response only addresses that the root cause for complaints #'s [REDACTED] and [REDACTED] were investigated. You do not address how the firm will prevent this problem from recurring.

11. Procedures that define the responsibility for review of non-conforming product were not complete, as required by 21 CFR 820.100(a)(7).

The corrective action appears adequate since the procedure now describes how the review shall be conducted.

12. A process, whose results cannot be fully verified by subsequent inspection and test, has not been validated and approved according to established procedures, as required by 21 CFR 820.75. Specifically, the [REDACTED] has not been validated.

This deviation was also observed during the 1995 inspection. The current inspection revealed your firm still has not properly validated the [REDACTED]. The adequacy of your corrective action for this deviation cannot be determined since the supporting documentation is not in English.

13. Procedures to ensure that equipment is routinely calibrated and that equipment is marked with calibration status according to established procedures, as required by 21 CFR 820.72(a).

In order to determine if this corrective action is adequate provide a summary of the calibration process and requirements or recognized standards that are used during the calibration.

14. Acceptance procedures for inspections, tests, or other verification activities were not completely defined and documented, as required by 21 CFR 820.80(a). Specifically, for incoming inspection of [REDACTED] does not show the quantity accepted.

This corrective appears inadequate. You have adequately corrected the missing information on the [REDACTED] however, you do not address the steps taken to prevent this problem from recurring.

15. The acceptance status of product was not clearly identified, as required by 21 CFR 820.86.

This corrective action appears adequate. A new marking in the incoming inspection area has been introduced with the (translated) text [REDACTED]. Additionally, the procedures have been revised and states that non inspected goods, not placed in quarantine area, shall clearly be marked with the document, [REDACTED].

16. Schedules for the adjustment, cleaning or other maintenance of equipment were not established, as required by 21 CFR 820.70(g)(1).

Your corrective action states a maintenance schedule has been developed for the [REDACTED], however, this document is not in English. Furthermore, it is unclear if other equipment contains maintenance schedules.

17. Software validation activities for computers or automated data processing systems used as part of production have not been documented, as required by 21 CFR 820.70(i).

Your corrective action appears inadequate. You have provided validation documents titled, [REDACTED] and the document "Validation test report, [REDACTED] dated [REDACTED], which are from the software supplier, [REDACTED]. Once again, the adequacy of the documents cannot be determined since they are not in English.

18. Suppliers were not evaluated and selected on the basis of their ability to meet specified requirements, as required by 21 CFR 820.80(b). Specifically, no review of data as the basis for selection of suppliers could be provided.

Your corrective action states, "Registration of the supplier's ability to meet specified requirement can now be performed [REDACTED]. In the near future, when data have been recorded, we will be able to review the data." This corrective action appears adequate.

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 regulation. The specific violations noted in this letter and in the form FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA-483. We have reviewed your response and as discussed above, we have determined most of your corrective actions are inadequate.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information in to account when considering the award of contracts.

Given the serious nature of these violations of the Act, all devices manufactured by Danplex A/S in Odense SV, Denmark may be detained upon entry into U.S. until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified your products may resume entry into this country.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you are taking to correct the violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction should be included with your response to this letter. If documentation is not in English, please provide the English translation to facilitate our review.

Your response should be sent to the attention of Mr. Patrick B. Weixel, Dental, ENT, and Ophthalmic Devices Branch, at the letterhead address.

Sincerely yours,

A handwritten signature in cursive script that reads "Larry Spears".

Larry Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health