



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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FDRGS

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Food and Drug Administration
2088 Gaither Road
Rockville MD 20850

FEB 11 1998

WARNING LETTER

Ref:OC:11-1777

via FEDERAL EXPRESS

• Mr. Gregg V. Volkenberg
General Manager
Optech Systems Corporation
100 Wildcat Road
North York, Ontario
CANADA M3J 2Z9

Dear Mr. Volkenberg:

Our review of your report of November 20, 1997, Accession No. 9722129, on the Distance Measuring Device model Attendant 100-EF and the Attendant 100 family indicates that these products fail to comply with the Federal Performance Standard for Laser Products as follows:

1. 21 CFR 1040.10(c). Based on the data provided in your report, we find the products are misclassified in that the energy of a single pulse exceeds the accessible emission limit of Class I for that pulse duration and the average power exceeds the limit of Class I for average power. As a result, the products are Class IIIb and also fail to comply with the following requirements of the standard applicable to Class IIIb laser products.
2. 21 CFR 1040.10(f). The products fail to comply with the performance requirements applicable to Class IIIb laser products.
3. 21 CFR 1040.10(g). The products fail to comply with the labeling requirements applicable to Class IIIb laser products.
4. 21 CFR 1040.10(h). The user, promotional, and service information fail to comply with the applicable requirements.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a

foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have been shipped to each importer in the United States. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must:
 - (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Based on the above findings, the Center for Devices and Radiological Health (CDRH) declares that Optech Systems Corporation has failed to conduct a testing program which ensures compliance with the applicable performance standard. The CDRH therefore, under authority of 21 CFR 1010.2(c), disapproves the testing and quality control program for the ATTENDANT 100 family products at your North York, Ontario, Canada plant.

This disapproval means that your firm is prohibited by Sections 534(h) and 538 of the the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,
2. introducing or importing products into the United States (U.S.) commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and
3. introducing or importing into the U.S. commerce any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U. S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved.

To resolve this matter, you must submit all the information required under 21 CFR 1002.10 such that the CDRH can determine that Optech Systems Corporation is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices.

The CDRH will advise you whether your submittal is satisfactory.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Minneapolis District Office, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, Minnesota 55401. If you have further questions on these requirements, please contact Dale Smith of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Primary Sensors, Inc.
P. O. Box 389
Hibbing, Minnesota 55746