

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1265B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600WARNING LETTER

March 18, 1997

WL-17-7

Gus Searcy
President
Automated Voice Systems, Inc.
17059 El Cajon Avenue
Yorba Linda, CA 92886

Dear Mr. Searcy:

During an inspection of your manufacturing facility conducted between February 7 to 21, 1997, our investigator determined that your firm manufactures powered environmental controllers intended for use by patients to operate environmental control functions. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our 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, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to control written manufacturing specifications and processing controls to assure that a device conforms to its original design or any approved changes in that design [21 CFR 820.100]. For example, our investigation determined that your firm failed to ensure that all changes made to your Mastervoice ECU powered environmental controller and the supporting justification for these changes were subject to controls as stringent as those applied to the original design specifications. Additionally, your firm has not established any specifications for the software components for the Mastervoice ECU powered environmental controller.

2. Failure to ensure that device history record(s) demonstrate that the a device is manufactured in accordance with the device master record [21 CFR 820.184]. For example, our investigation disclosed that your firm has not documented any of the finished device testing, including results and subsequent releases for the Mastervoice ECU powered environmental controller.

3. Failure to routinely calibrate, inspect, and check according to written procedures all production and quality assurance measurement equipment [21 CFR 820.61]. For example, our investigation disclosed that your firm has no written procedures for the calibration and preventative maintenance, including schedules for the measurement equipment used in the production and finished device testing of your Mastervoice ECU powered environmental controller.

4. Failure to have a designated individual prepare, date and sign your device master record for the Mastervoice ECU powered environmental controller [21 CFR 820.181].

Additionally, a review of our records indicates that your firm has not submitted any premarket notification, Section 510(k) for your Mastervoice ECU powered environmental controller. Promotion and distribution of the device with unsubstantiated claims and without submission of premarket notification, Section 510(k) may result in the device being adulterated under Section 501(f)(1)(B) and misbranded in within the meaning of 502(o) of the Federal Food, Drug and Cosmetic Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. 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 firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until it has been determined that corrections are adequate, 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 pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates For Products For Export will be approved.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Such actions includes, but is 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 anticipated date that your facility will be ready for reinspection.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
1990 MacArthur Boulevard
Irvine, California 92612-2445

Sincerely,



Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814