



DEPARTMENT OF HEALTH & HUMAN SERVICES

9/1906

Food and Drug Administration  
Denver District Office  
Building 20 – Denver Federal Center  
P.O. Box 25087  
Denver, Colorado 80225-0087  
TELEPHONE: 303-236-3000

October 29, 2001

**WARNING LETTER**

**RECEIVED**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. James Bert Bunnell  
Chief Executive Officer  
Bunnell, Incorporated  
436 Lawndale Drive  
Salt Lake City, Utah 84115

Ref. # - DEN-02-04

Dear Mr. Bunnell:

An inspection of your firm located at 436 Lawndale Drive, Utah was conducted between September 10 - 14, 2001, by Investigator Nicholas R. Nance. This inspection determined that your firm manufactures high frequency jet ventilators and accessories for neonatal use. These ventilators 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/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

Failure to conduct management reviews to determine the suitability and effectiveness of the quality system, as required by 21 CFR 820.20(c). For example, not all sources of quality data are reviewed, tracked or trended by management, such as sub-assembly reject data and finished product testing failures. Management review meeting procedures do not stipulate the sources of quality data to be reviewed, how data is to be analyzed or how the results of reviews will be documented.



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records were found to be missing sampling plans used at the time of the inspection, as required by your firm's procedures. Other discrepancies noted on inspection records included incorrect lot sampling sizes, missing temperature recordings or the acceptance/rejection status of the lot.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the regulations, as well as other requirements of the Act. Continued distribution of violative devices may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all warning letters regarding medical devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing within 15 working days of receipt of this letter, of any steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, P. O. Box 25087, Denver, CO 80225-008, Attention: Regina A. Barrell, Compliance Officer. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,



Thomas A. Allison  
District Director