



DEPARTMENT OF HEALTH & HUMAN SERVICES

94374d  
Food and Drug Administration

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

October 24, 2003

Ref: 2004-DAL-WL-06

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Ms. Lauralee Thornton, President  
Airway Management, Inc.  
6617 Park Lane  
Dallas, Texas 75225

Dear Ms. Thornton:

Our review of information collected during an inspection of your firm located at the above-referenced address on August 27 and September 4, 2003, revealed that your firm manufactures the Thornton Adjustable Positioner (TAP<sup>®</sup>), a dental device intended for alleviating night time snoring and obstructive sleep apnea. These products are devices as defined in 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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure to establish and maintain procedures for quality audits and the conduct of such audits [21 CFR 820.22]. See FDA-483 Item 1.
2. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities [21 CFR 820.25(b)]. See FDA-483 Item 1.

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3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)]. Our inspection documented that your firm did not have any complaint handling procedure.
4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50]. Your firm failed to (a) establish and maintain requirements, including quality requirements, that must be met by your contract manufacturer; and (b) evaluate this contract manufacturer on the basis of its ability to meet your quality requirements. See FDA-483 Item 4.
5. Failure to establish and maintain procedures for acceptance of incoming products [21 CFR 820.80(b)]. Your firm has no procedure defining how your firm inspects or verifies dental device components manufactured by the contract manufacturer, and documents the results of acceptance or rejection. See FDA-483 Item 6.
6. Failure to establish and maintain procedures to ensure that device history records (DHR's) for each lot, batch, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record (DMR) [21 CFR 820.184]. Your firm has no production records for the Thornton Adjustable Positioner (TAP) devices. See FDA-483 Item 11.
7. Failure to establish and maintain procedures for the identification, documentation, validation or verification, review, and approval of design changes before their implementation [21 CFR 820.30(i)]. Your firm initiated a design change to the TAP device in order to introduce a newer device (Model TAP-II) without establishing any procedures to control this design change. See FDA-483 Item 2.

We have received your letter, dated September 18, 2003, responding to the inspectional observations listed on the Form FDA-483 that was issued to you at the close of our inspection on September 4, 2003. We noted that you have not signed the letter to confirm your firm's official response. You responded that these inspectional observations resulted from your misunderstanding of your firm's GMP status. When FDA cleared the 510(k) for your Thornton Adjustable Positioner device in K972061, FDA informed your firm that your devices were subject to the general control provisions of the Act. These provisions include requirements for annual registration and listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Our inspection documented that your firm has been manufacturing the devices

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without establishing a quality system since 1997. Nevertheless, you promised to take corrective actions and attached a schedule for completing each GMP activity. You expect to complete all corrections by January 15, 2004. Your response will not be considered satisfactory until your firm has completed all corrections and provided a final status report by the promised deadline.

Your letter does not address two non-GMP observations that were not listed on the FDA-483 but were discussed with you during the inspection. These observations cited: (a) Your devices failed to meet the general labeling requirements to identify the name and place of business of the manufacturer on the device label as required by 21 CFR 801.1(a); and (b) Your devices failed to bear the prescription legend on the device label as required by 21 CFR 801.109(b)(1). Although you orally promised to the investigator that you would correct these issues, you have not confirmed your commitments in your September 18, 2003 letter. Your response will not be considered satisfactory until you have addressed these issues.

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 the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close 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. You also must promptly initiate permanent corrective and preventative action on your quality system.

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.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions concerning this matter, you may contact Mr. Ta at (214) 253-5217.

Sincerely,

  
Michael A. Chappell  
Dallas District Director

MAC:txt

cc:

Dr. William Keith Thornton  
D.D.S., Chief Operating Officer  
Airway Management, Inc.  
6617 Park Lane  
Dallas, Texas 75225