



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

711-
91538d
60 8th Street, N.E.
Atlanta, Georgia 30309

July 13, 2001

VIA FEDERAL EXPRESS

Mark Ferreira
President
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85944

WARNING LETTER
(01-ATL-61)

Dear Mr. Ferreira:

An inspection of your facility, Paragon Healthcare Corporation, located at 107 Corporate Drive in Spartanburg, South Carolina, was conducted between February 27 and March 9, 2001, by Investigator Claudette D. Brooks. Our investigator found that you continue to operate as a third party reprocessor of a variety of products to include electrophysiology catheters, sequential compression devices, and syringes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you reprocess and distribute to be adulterated within the meaning of Section 501(h) of the Act. These deviations from the QSR include:

1. Failure to establish and maintain a design history file for each type of device that contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the design control provisions of the Quality System regulation, as required by 21 CFR 820.30(j). For example:
 - a. Paragon Healthcare Corporation (Paragon) did not have studies or data for a variety of "open-unused" devices; i.e., sutures, grafts, drapes, drains, and gowns. No supporting data could be provided to establish that ethylene oxide sterilization had no adverse effect on the product functionality or packaging materials.

- b. Paragon failed to perform risk assessments and design reviews when new devices were selected for reprocessing, and failed to maintain design history files on these devices.
2. Failure to maintain device master records which include, or refer to, the location of quality assurance procedures and specifications, packaging and labeling specifications, and maintenance procedures and methods, as required by 21 CFR 820.181. For example, Paragon had not established procedures and specifications for "open-unused devices" reprocessed by the subcontractor, to include receipt, relabeling, release, distribution, and maintenance of device history records by the subcontractor.
3. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the requirements of the Quality System regulation, as required by 21 CFR 820.184. For example, two reprocessed lots were chosen at random for review, #010245 (grafts) and #000185 (sutures). No sterility test results or product labeling were available for review. The only record on file was the shipping invoice. Processing records, to include sterility testing, had to be retrieved from your contract processor. There was no documentation that anyone at Paragon had reviewed the processing information prior to releasing these devices to your customers.
4. Failure to establish and maintain procedures for validating the device design to ensure that devices conform to defined user needs and intended uses, as required by 21 CFR 820.30(g). For example:
 - a. Paragon failed to adequately perform design validation, in that you have not determined the negative consequences of multiple reprocessing and have not established a maximum number of reprocessing operations for cardiovascular catheters. A maximum number is not established in any formalized procedure and you could provide no documentation to demonstrate that a limit on the number of reprocessing operations has been established. Our investigator was told that the maximum number of reprocessing operations is decided collaboratively with each customer. A review of customer specifications revealed catheters to be reprocessed between times.
 - b. Paragon did not follow the established procedures for evaluating product design when additional devices were selected for reprocessing. Your Product Design procedure required that a meeting be held with Marketing, Operations, and Quality to consider the addition of new products. Tourniquet cuffs were added in January 2000 and there was no indication that the above meeting was held and that all required personnel had appropriate input. No risk assessment was performed and no reviews were conducted other than a Validation Equivalency. Other devices were added for reprocessing that did not go through the design control evaluation.

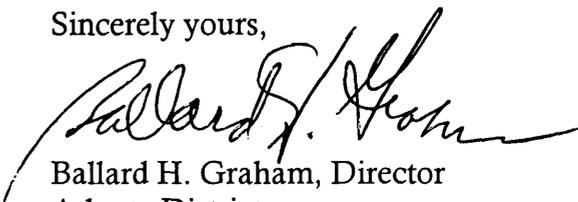
5. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198. For example, Paragon had failed to implement appropriate complaint handling procedures. Complaints were not being investigated to identify existing or potential causes of nonconforming product or other quality problems. Of the eight complaints selected for review, five lacked evidence of a detailed investigation (#C0089, C0112, C0141, C0132, and C0179).
6. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), to include procedures for investigating the causes of nonconformities relating to product, processes, and the quality system; identifying the action needed to correct and prevent recurrence of nonconforming product and other quality problems; and verifying or validating the CAPA, as required by 21 CFR 820.100. For example, there is no evidence of a detailed investigation, or documentation of action taken to prevent recurrence of nonconforming product, for complaints such as the failure of catheter to ablate, electrical failure, catheter breakage during use, and incorrect labeling.
7. Failure to base sampling plans on a valid statistical rationale, as required by 21 CFR 820.250. For example, Paragon had not defined or established a statistical rationale for the number of devices inspected by QA prior to pre-sterilization or post-sterilization release. The investigator noted that the observation was corrected in that a new procedure was prepared, however, there was no verification of the implementation of this new procedure. Verification of the entire corrective action will need to be assessed during the next inspection.
8. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a). For example, Paragon had not established procedures for placing customer devices on hold status although at least [REDACTED] EP catheters are on hold. Receiving procedures did not define the handling of unapproved/unsuitable customer products. The investigator noted that the observation was corrected in that a new procedure was prepared, however, there was no verification of the implementation of this new procedure. Verification of the entire corrective action will need to be assessed during the next inspection.

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 regulations. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to and discussed with Deanna Phillips, Quality Systems Manager. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 could be symptomatic of underlying problems in your firm's 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. We acknowledge that some corrections were initiated to the investigator's observations during, and subsequent to, the inspection.

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 deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Deanna Phillips, Quality Systems Manager
Paragon Healthcare Corp.
107 Corporate Drive
Spartanburg, South Carolina 29303