



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
Atlanta District Office

HEI-35 d 1707b

60 8th Street, N.E.  
Atlanta, Georgia 30309

April 14, 1998

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

William T. Stover  
Chairman & Chief Executive Officer  
Paragon Healthcare Corporation  
2311 Biscayne Drive  
Suite 201  
Little Rock, Arkansas 72227

**WARNING LETTER**

Dear Mr. Stover:

An inspection of your firm located in Spartanburg, South Carolina, was conducted on January 12-14 & 26, 1998. Our investigator found that you are operating as a third party reprocessor of electrophysiology catheters. These catheters are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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

1. Failure to validate a process with a high degree of assurance where the results of the process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example:
  - a. Cleaning
    - i. A total of ten catheters were tested in three runs. Of these, two of three catheters from run 2 and two of three catheters from run 3 did not meet acceptance criteria established for final protein on cleaned devices, and one of three catheters from run 3 did not meet acceptance criteria established for endotoxin reduction.

- ii. There was no Recovery Control Catheter for one of the three validation runs.
  - iii. The specifications of the cleaning process and the types of catheters used during the validation study were not documented.
- b. Ethylene Oxide Sterilization
- i. Biological indicators used in the validation study were not tested for population and resistance, as required by the protocol.
  - ii. Validation loads consisted of [REDACTED] cases, whereas production runs routinely consist of [REDACTED] cases.
- c. Packaging
- i. The temperatures used in the validation study, 170°, 185°, and 200°, were different from those specified in the protocol, 185°, 195°, and 205°, and did not support the packaging specification, i.e., [REDACTED].
  - ii. Parameters of the [REDACTED] sealer used during the packaging validation study, such as operating pressure and dwell time, the operating pressure of the compressor and the current (amps and voltage) of the sealer, were not documented.
- d. Test Methods
- i. The test methods used to determine catheter acceptability after cleaning have not been validated.
2. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example:
- a. SOP TM00001 "Test Method" is not sufficiently detailed or objective to adequately describe the acceptance criteria.
  - b. The finished device testing procedures are inadequate to measure the degree of fatigue of internal steering wires for cardiac ablation catheters and assure safe and effective use of the devices.
  - c. The maximum number of reprocessing operations for cardiovascular catheters is not identified in any written procedure, and no documentation was provided to demonstrate that a limit on the number of reprocessing operations had been established.

- d. Pyrogen testing is not performed.
3. Failure to implement procedures to adequately control environmental conditions which could reasonable be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, there is no documentation that, prior to 1/98, daily sanitization of work and test benches was conducted as required by "SOP PS00001 - Decontamination."
4. Failure to implement procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, vendor surveys were not conducted as required by "SOP-0028 Vendor Survey Report".

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 Inspectional Observations (FDA 483) was issued to and discussed with Mr. Kerry M. Hicks, President/CEO. 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 serious 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.

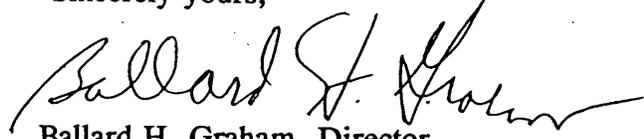
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no request for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

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.

We are in receipt of the February 16 response from your firm to the FDA 483. Our review comments to that response will be forwarded in another letter. You may reference the February 16 letter in your Warning Letter response, if you feel that it adequately addresses any of the issues raised in this letter. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ballard H. Graham, Director  
Atlanta District

Enclosure

cc: Kerry Hicks, President  
Paragon Healthcare Corporation  
105 Corporate Drive, Suite A  
Spartanburg, SC 29303