



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

RECEIVED  
12/14/97  
-1 FI-35  
6

Food and Drug Administration  
One Montvale Avenue  
Stoneham, Massachusetts 02180  
(617)279-1675 FAX: (617)279-1742

WARNING LETTER

NWE-04-98W

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

November 17, 1997

Mr. John F. White  
President and CEO  
Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114

Dear Mr. White:

During inspections of your firm located in Braintree, MA from May 23, 27, 28, 30, June 13, July 2, 3, 7, 11, 15, 1997 and July 29-August 1, 5, 6, 12, 13, 18, 20, 28, 1997, Investigators determined that your firm is responsible for the manufacture and distribution of medical devices, including Plasma Collection Systems (PCS, PCS2) and related disposable sets. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspections revealed major deficiencies in your Corrective and Preventive Action System, for example, problems were identified in your complaint area and servicing area which do not allow your firm to assure that all your product nonconformities are identified and handled in a uniform manner. These above stated inspections 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 regulations, as specified in Title 21 Code of Federal Regulations, (21 CFR) Part 820<sup>1</sup>, as follows:

---

<sup>1</sup> The deviations described in this Warning Letter would also be violations of the Good Manufacturing Practice Regulations established in 1978.

- 1 Failure to maintain complaint files that contain any written, electronic or oral communication that alleges deficiencies related to the identity, durability, reliability, safety or effectiveness or performance of a device after it is released for distribution. For example, your Complaint Handling Procedure, SOP IV-1 Rev U did not include any instructions for the maintenance of service records for Plasma Collection System devices that occur after thirty (30) days of installation. These include service records that indicate that donor overdrafts were occurring on the serviced device.
- 2 Failure to review, evaluate and investigate any complaint involving the possible failure of a device. For example:
  - a Service reports of overdrafts are not reviewed, evaluated or maintained as complaints, even though your own procedure defines incidents of overdrafts as "critical complaints"
  - b A review of Product Investigation Reports (PIR's) and service reports of overdrafts revealed that your documentation of these events does not indicate the volume of plasma that was overdrawn in any of the [REDACTED] service reports reviewed or of the [REDACTED] PIR's reviewed. This lack of information precludes your firm from performing an adequate investigation of the complaint.
- 3 Failure to establish and maintain instructions and procedures for performing and verifying that your servicing of Plasma Collection System devices meet specified requirements, and the failure to analyze such service reports with appropriate statistical methodologies in order to feedback this pertinent information into your corrective and preventive action system. For example, there are no procedures for analyzing Commercial Plasma Equipment service reports. From January to July 1997, [REDACTED] power supply boards were shipped to one plasma center for PCS2 devices that were installed from September to November 1996. There was no record of any investigation that was made as to why these boards were sent out. Subsequent investigation by your firm determined that certain power supply boards contained an unapproved material in a component that caused the power supply boards to fail prematurely in the field.
- 4 Failure to have an adequate corrective and preventive action system which allows for the analysis of service records, complaints, returned product and other quality data using a statistical methodology to detect recurring product quality. Your system also fails to investigate the cause of nonconformities and fails to verify that the corrective or preventive action taken, is effective. It also fails to identify how and when to implement appropriate procedures to correct and prevent the identified quality problems. For example, from February 1996 to August 1996, Haemonetics had received numerous complaints regarding filter chamber leaks on the LN 620 Harness. As a result of these complaints, Haemonetics initiated an ECO in March 1997, seven (7) months later, which called for the replacement of the filter chamber assembly with a plug style assembly.

The above stated inspections also revealed that the LN 994CF and the LN 994F Platelet Collection Filtration Kits manufactured by your firm are misbranded within the meaning of Section 502(o) of the Act, in that a notice or other information respecting significant changes in design, materials, and intended use, made to these devices, were not provided to the FDA as required by 21 CFR Part 807.81(a)(3)(i) and (ii). In this case, the [REDACTED] leukoreduction filter, which was 510(k) cleared for use as a bedside red blood cell filter, was integrated into a continuous filtration apheresis harness set (LN994CF), and a harness set that performs leukoreduction at the end of the apheresis process (LN 994F), and distributed without prior 510(k) clearance. These modifications raise new issues of safety and effectiveness.

Additionally, since no notice or other information respecting the significant changes were made for the above two devices, they would be adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are class III devices under Section 513(f) and do not have approved applications for premarket approval in effect pursuant to Section 515(a) or approved applications for an investigational device exemption under Section 520(g).

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. The specific violations noted in this letter and in the FDA 483 issued at the close-out 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 action.

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 premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

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

Please notify this office 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 prevent the recurrence of similar violations. Your response should be sent to Karen N. Archdeacon, Compliance Officer, United States Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Warning Letter

November 17, 1997

We have received and reviewed your letters dated August 5, 1997 and September 17, 1997 that were in response to our FDA-183's issued to your firm on July 15, 1997 and August 28, 1997. In addition to the issues discussed in this Warning Letter, we have provided comments to your most recent response dated September 17, 1997. These comments, as well as the two referenced FDA 183's, are attached as an addendum to this letter.

We also understand that your firm has requested a meeting with the Center for Biologics Evaluation and Research, (CBER) to discuss 510(k) issues. We believe that a meeting between Haemonetics, CBER, CDRII and the district would be appropriate to discuss the 510(k) issues as well as the content of the Warning Letter and the deviations noted during the recent inspections. Please contact Ms. Archdeacon to arrange such a meeting.

If you have any questions concerning this matter, please contact Ms. Archdeacon at 781-279-1675. Fax: (on 113)

Sincerely yours



John R. Marzilli  
District Director  
New England District Office

Attachments

cc: Lisa Lopez  
Corporate Vice President and General Counsel