



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

d16476

11/13/96  
AT 5-55

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

November 13, 1996

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

David R. Court  
President and CEO  
Dynamic Systems, Inc.  
5002 North Royal Atlanta Drive  
Suite P  
Tucker, Georgia 30084

**WARNING LETTER**

Dear Mr. Court:

During a September 11-17, 1996 inspection of your firm, our investigator found that you are manufacturing and distributing a controller for powered wheelchairs. The Peachtree Proportional Head Control Unit (PHC-2) is a medical device within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The PHC-2 is misbranded within the meaning of Section 502(o) of the Act, in that the device was manufactured in an establishment not duly registered under Section 510, was not included in a list required by Section 510(j), and a notice or other information respecting this device was not provided to the Food and Drug Administration as required by Section 510(k) of the Act.

In addition, the PHC-2 is adulterated under Section 501(f)(1)(B) of the Act, in that it is a Class III device under Section 513(f) and does not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) or an approved application for investigational device exemption under Section 520(g). The continued distribution of this device is a serious violation of the Act.

Investigator Hilscher also documented numerous significant deviations from the Good Manufacturing Practice for Medical Devices (GMPs) as set forth in Title 21, Code of Federal Regulations (21 CFR), Part 820. These deviations cause the device you manufacture to be adulterated within the meaning of Section 501(h) of the Act.

**You have failed to establish and implement a quality assurance program that is appropriate for the medical device manufactured and distributed by your firm. Quality assurance procedures failed to ensure that the PHC-2 units conformed with finished device specifications prior to release. Your quality assurance program failed to respond to device quality problems identified from sources such as consumer complaints. Your quality assurance program is responsible for identifying, recommending, and providing solutions for quality assurance problems and verifying the implementation of such solutions.**

**You have failed to establish a formalized device master record for the PHC-2. This master record must be prepared, dated and signed by a designated responsible individual. The master record should include device specifications, production process specifications, quality assurance procedures and specifications, and packaging and labeling specifications. Any changes in the device master record should be authorized in writing by the designated individual. Your firm has maintained no documentation for any of the changes made to the original design of the PHC-2 device. There are no change control procedures in place to document the numerous changes made to the units distributed.**

**You have failed to maintain device history records which demonstrate that the devices were manufactured in accordance with the device master record or established specifications. No attempt is made to document production steps in the manufacturing of your device. The available records fail to include which version of the device was manufactured, which options were included, and if any custom interfaces were added to the unit.**

**You have failed to establish a review of finished devices to assure that device specifications have been met prior to release. There is no documentation of calibration results or when quality assurance testing was conducted on the units. No documentation was available to indicate any review by quality control or quality assurance personnel prior to final release of the PHC-2 devices.**

**You have failed to implement an appropriate system to assure that all written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of your device is reviewed, evaluated, and maintained. No complaint file is maintained at your firm. You must also develop, maintain, and implement written procedures for the handling of complaints which are subject to the Medical Device Reporting requirements of 21 CFR, Part 803.**

**You have failed to implement planned and periodic audits of the quality assurance program. These audits should be performed in accordance with written procedures by an appropriately trained individual. No such internal audits have been conducted.**

**You have failed to maintain any records of acceptance and rejection of incoming components. A designated individual should accept or reject all incoming components in accordance with written procedures.**

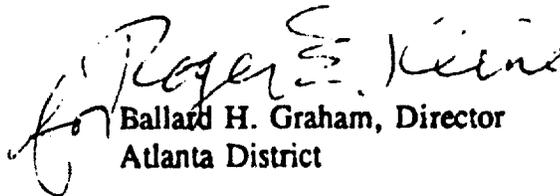
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 are 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. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests 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 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 (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 will be forwarding you information to assist in the submission of the required registration and device listing forms. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

  
Ballard H. Graham, Director  
Atlanta District