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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Refer to: CFN 1117676

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4040

October 2, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Timothy Ellis, President  
Dynex Technologies, Incorporated  
14340 Sullyfield Circle  
Chantilly, Virginia 22021

Dear Mr. Ellis:

During a Food and Drug Administration (FDA) inspection of your firm located in Chantilly, Virginia, conducted between August 19, 1997 and September 24, 1997, our investigators evaluated the manufacturing of MRX microplate readers. MRX microplate readers are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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, manufacturing, packing, storage, or installation, are not in conformance with the Quality System Regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to ensure that finished devices meet acceptance criteria prior to distribution.
2. Failure to validate the MRX reader manufacturing process.
3. Failure to establish written and approved reprocessing procedures covering nonconforming finished devices that were re-worked.
4. Failure to adequately control inspection, measuring, and test equipment as follows:
  - a) Failure to validate finished device testing software, some of which were incorrectly programmed.

- b) Test software failed to contain a test process/calculation to assure that finished device accuracy specifications were met.
  - c) Failure to establish calibration procedures for calibration plates used in in-process and finished device testing.
  - d) Failure to have written and approved procedures in place for collecting reference readings as part of test equipment calibration.
  - e) Failure to establish written and approved manufacturing procedures for finished device test software for MRX multi board and single board devices.
5. Failure to review, evaluate, and record all customer complaints or to follow approved SOPs. No records were available to document that complaints involving failure of MRX devices to meet specifications were reviewed for possible failure investigation or Medical Device Reportable events.
6. Failure to document training for employees who receive reports on product performance. For instance, no training documentation was available for technical service employees responsible for maintaining the complaint (CAR) and failure investigations database. Additionally, no training documentation was available for field service employees responsible for repairing MRX instruments that have malfunctioned.
7. Failure to adequately control finished MRX reader acceptance activities, as there was no documentation available to show that accuracy specifications had been met or reviewed.
8. Failure to have handwritten changes made to assembly operations procedures approved by the Manufacturing Engineer and the Manufacturing Manager, as required in Document Control SOP #120. These changes were implemented without approval.
9. Failure to maintain written and approved SOPs for the following production and process controls:
- a) distribution of finished devices;
  - b) incoming goods inspection and receiving;
  - c) equipment maintenance;

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- d) re-inspection of all inventory and/or in-process material of the same lot number when nonconforming conditions are identified.

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 closeout 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 actions.

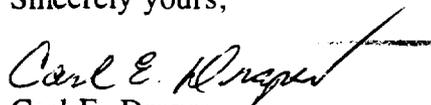
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the Quality System Regulations deficiencies are reasonably related 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.

We acknowledge your promise made at the close of the inspection to correct the deviations. We further acknowledge our meeting scheduled for October 7, 1997. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action 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 15 working days of receipt of this letter or at the time of our meeting 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 should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200. Mr. Miller can be reached at 703-235-8440, extension 504.

Sincerely yours,

  
Carl E. Draper  
Acting Director, Baltimore District