



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-29

March 2, 1998

Kevin O. Dean, President
Burke/Neutech Medical Systems, Inc.
1765 Commerce Avenue N.
St. Petersburg, Florida 33716

Dear Mr. Dean:

We are writing to you because on December 16 through 23, 1997, FDA Investigator Christine Humphrey collected information that revealed serious regulatory problems involving the LSI 6000 and LSI 5200 thermal regulating systems and the ST 1000 electronic portable cold therapy system (Class II), for which your firm is the manufacturer and distributor.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the 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 the manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to validate manufacturing processes for the LSI 6000 and 5200 and the ST 1000 assuring that devices conform to specifications, e.g., there is no documentation covering any process controls necessary to assure conformance to specifications.

- Failure to establish and implement a quality assurance program that is appropriate and specific to each device manufactured including management responsibility and oversight.
- Failure to establish and maintain an adequate complaint handling system, e.g., there is no established system for the assignment of complaint handling responsibility, maintenance of complaint records., preparation of investigation records, and the documentation of complaint analysis.
- Failure to establish and maintain complete Device Master Records (DMR) and Device History Records (DHR) to assure all specifications and quality assurance requirements are met including component, production process, equipment, and sterilization process parameters.
- Failure to establish and maintain a written MDR procedure to assure the timely and effective identification, evaluation of events subject to MDR, e.g., documentation related to the LSI 6000 (serial #s 3064, 3077, and 3108) fails to include follow-up investigations, conclusions and any changes made to correct the nonconformance.
- Failure to establish and maintain a written MDR procedure to identify, communicate, and evaluate events subject to medical device reporting.
- Failure to establish and maintain procedures for corrective and preventive actions, e.g., there were no documented procedures to assess non-conforming product nor any actions taken to prevent future nonconformities.
- Failure to assure that finished devices meet specifications prior to release and distribution, e.g., final inspections of the LSI 6000 revealed several devices were released prior to the completion, recording, and review of the burn-in test.
- Failure to establish and maintain formal approval procedures to include production and process changes and document approval assuring conformance to specifications and that all changes are effectively communicated to manufacturing personnel.
- Failure to establish, document and maintain complete Device Master Records (DMR) for the LSI 6000 and 5200, and the ST 1000, e.g., the DMRs fail to include all necessary information or the location of information relative to

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manufacturing procedures, specifications, testing equipment, and labeling.

- Failure to maintain and establish training procedures and records for all personnel.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. 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 Inspectional Observations (FDA 483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. We understand that you have or are in the process of moving your manufacturing facility from Florida to Tennessee. It was reported that you plan to duplicate the St. Petersburg facility in Nashville, Tennessee and that other Medcorp, Inc. facilities would also be located at this single location. Because of your move to Tennessee we are notifying the Nashville District Office of our regulatory findings and providing them a copy of this Warning Letter. Please direct your response to Howard Lewis, Director of Compliance, Food & Drug Administration, Nashville District, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Howard Lewis at (615) 781-5388, ext. #124.

Sincerely,

A handwritten signature in cursive script that reads "Douglas D. Tolen". The signature is written in black ink and is positioned above the printed name and title.

Douglas D. Tolen
Director, Florida District