DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 9 1483d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 10, 2001

WARNING LETTER

Mr. David A. Jenkins
President and CEO
EP MedSystems
575 Route 73 N. Bldg. D
West Berlin, New Jersey 08091

FILE NO: 01-NWJ-29

Dear Mr. Jenkins:

During an inspection of your firm located at 575 Route 73 N., West Berlin, New Jersey, between March 14 and May 7, 2001, our investigator determined that your firm manufactures cardiac catheters. Cardiac catheters are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that your cardiac catheters 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, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820 as follows:

1. **Your management with executive responsibility failed to ensure that an adequate quality system has been established and maintained as required by 21 CFR 820.20. For example:**

   a. Although your management representative is authorized to write procedures, your management with executive responsibility has failed to ensure their implementation. For example, although your management representative issued Design Control Procedure DOC 1004 in January 1997, your firm failed to follow this procedure.

   b. Although your management representative issued corrective action requests resulting from internal audits, your management with executive responsibility failed to ensure their timely correction. The lack of timely corrective actions was brought to the attention of your management with executive responsibility during management's' review meetings.

   c. Your firm has made numerous design and process changes without concurrence from your quality department.

d. Your firm failed to provide training in current good manufacturing practices to all personnel performing quality control and manufacturing activities.

2. Your firm failed to implement design controls as required by 21 CFR 820.30 for the following changes:

a. A change was made in the Alert and Alert TD labeling regarding changing the size of the recommended guidewire from .021" to 025". There was no verification/validation to support this change.

b. To accommodate the use of nonconforming material, a backshell with a smaller inner diameter of [redacted] was used instead of [redacted] There was no verification/validation to support this change.

c. The spacing of the electrodes on the electrophysiology catheter was changed in January 1999. There was no verification/validation to support this change.

3. Your firm failed to verify/validation several process deviations as required by 21 CFR 820.75:

a. Your firm deviated from your Alert catheter manufacturing process by attempting to fit an adapter backshell to the backshell connector tubing, first with [redacted], then by [redacted] the tubing to [redacted] it. Your analysis of complaints 0067, 0069, 0070, 0071, 0073, and 0075 indicates that this process deviation may have caused these complaints.

b. Your firm deviated from your Alert catheter manufacturing process by using an [redacted] in place of [redacted]. This deviation was noted on Work Orders 6144-6147 and 6150.

c. Contrary to your sampling plan which is Mil-Std. 105E with an AQL of [redacted] and a general [redacted] inspection level, your firm accepted and used [redacted] pieces of 7.5 Fr. Alert tubing lot #5352 dtd. 1/5/01 where there were 59 failures out of 192 satellite lumen measurements from 32 pieces of tubing.

4. Your firm did not follow your sterilization load configuration as identified in DOC 2009 "Boxing and Shipment for Sterilization of Finished Product." In addition, your firm failed to have data to support the equivalency of "dunnage" product to actual catheter product.

5. Your firm failed to validate several computer databases that are used for quality functions including your Access database, your [redacted] software, and your MS Excel spreadsheet program as required by 21 CFR 820.70(i).

6. **Your firm failed to perform installation and operational qualification for the following pieces of equipment: the Fenn NF Swager, the thermoforming sealing machine used to seal the [redacted] to the [redacted], and the oven used to [redacted] the tubing after the swaging operation.**

Both this letter and the FDA 483 that was issued to your firm are 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 to you may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be system 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, requests for Certificates of Exportability to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations 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.

The agency is in receipt of your written response, dated May 24, 2001, to the FDA 483 issued to your firm on May 7, 2001. We acknowledge your firm's commitment to the Quality System Regulations; however, in order to complete our review, we need more documentation of your corrective actions. For example, please provide the reassessment information for each of the design and process changes that your firm has made. Please provide protocols and summary reports for the validations that your firm needs to complete.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054.

Sincerely,

Edward H. Wilkens, for
Douglas I. Ellsworth
District Director
New Jersey District