



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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Telephone (973) 526-6010

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

February 15, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

James L. Skaggs, Jr.
Assistant General Manager & Co-Owner
J-Lloyd Medical Inc.
415 Commerce Lane
Suite 7
West Berlin, New Jersey 08091

File No. 01-NWJ-18

Dear Mr. Skaggs:

During an inspection of your establishment located in West Berlin, New Jersey, between December 12-20, 2000, our investigators determined that your establishment manufactures cardiac balloon-catheters. Cardiac Catheters are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed serious deviations from the Quality System Regulation for medical devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These deviations cause your devices to be adulterated within the meaning of Section 501(h) of the Act.

Some of the specific deviations are as follows:

- Failure to perform and document finished product testing of catheters packaged during April and July 2000.
- Failure to monitor the Class 100,000 clean room to assure its adequate function. Specifically, the Class 100,000 area had not been re-certified since 1995 and the HEPA filters had not been changed since their installation in 1992. Microbial air and contact surface sampling was performed only once per year. In addition, the Air Particle counter was not calibrated according to the established schedule and continued to be used, and the humidity in the clean room was not monitored and controlled for approximately one month after the humidity gauge was discovered to be malfunctioning.
- Failure to implement design controls when the design of the pacing catheters was changed to include shrouds on the patient leads.
- Failure to perform and document design validation for the hexipolar pacing catheter.
- Failure to establish a written Medical Device Reporting (MDR) procedure.
- Failure to document post-sterilization seal integrity testing of the catheter packages.

This 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 on the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems with your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action to your Quality System.

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 Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. 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 these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure, injunction, and/or civil penalties.

Although your initial response, dated January 10, 2001, met the 15-day time frame for the Warning Letter Pilot Program, the response was not detailed enough for a complete evaluation of your corrective actions. We were unable to determine whether or not the actions appeared to be satisfactory or not, therefore, your firm is not eligible to participate in the Warning Letter Pilot Program. We have also received your second response dated February 1, 2001. Again, this response was not detailed enough for us to evaluate your corrective actions. Both responses have been made part of our official file.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Your response should include an explanation of each step being taken to identify and correct any underlying system problems so 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 necessary for the corrections to be completed.

Please address your response to: U.S. Food and Drug Administration, 10 Waterivew Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Edward-H Wilkins, acting for
Douglas I. Ellsworth
District Director