

dl697b

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

November 26, 1996

Ref: 97-DAL-WL-06

**WARNING LETTER****Certified Mail**  
**Return Receipt Requested**

Mr. Byron M. Jones, President  
J-F Medical Systems Intl., Inc.  
2440 Lacy Lane, Suite 101  
Carrollton, Texas 75006

Dear Mr. Jones:

During our July and August 1996 inspection of your facilities in Carrollton, Texas, our investigators determined that your firm manufactures cardiac catheter lab programmable diagnostic computer systems. These computer systems are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above referenced 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 their manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulations, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

Failure of the device master record to include device specifications, production process specifications, quality assurance procedures and specifications, and packaging and labeling specifications, as required by 21 CFR 820.181.

Failure to establish, implement and control written manufacturing specifications and processing procedures to assure that the device conforms to its original design or any approved changes in that design, as required by 21 CFR 820.100. For example, changes made to the CARES system and the addition of optional equipment packages were not adequately validated.

Failure to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications, as required by 21 CFR 820.198(b). For example, service reports and calls were not documented, reviewed, evaluated, and investigated as potential complaints.

Failure to adequately investigate any failure of a device to meet performance specifications after the device has been released for distribution, as required by 21 CFR 820.162.

Failure to have in place an adequate organizational structure and sufficient personnel to assure that the devices produced are manufactured in accordance with the requirements of the GMP regulation, as required by 21 CFR 820.20.

Failure to have written procedures for and to receive, accept, store, and handle device components in a manner designed to prevent damage, mix-up, contamination, and other adverse effects, as required by 21 CFR 820.80.

Failure to control or provide the proper environmental conditions for the electronics manufacturing operations, as required by 21 CFR 820.46. For example, electrostatic discharge (ESD) controls were not used.

In addition to the above stated GMP violations, our inspection revealed significant changes [redacted] modifications to other firm's devices and [redacted] options added to your device) were made to these devices after Section 510(k) submissions were found substantially equivalent. We acknowledge your commitment to evaluate these changes and make 510(k) submissions as appropriate. We also wish to advise you that commercial distribution of devices prior to receiving 510(k) clearance is a violation of the Act that could subject you individually as well as your firm to civil penalties of up to \$15,000 each per device distributed.

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.

We acknowledge your attorney's August through November 1996 responses concerning our investigator's observations as well as our September 3, 1996, discussions in our offices. It appears that your responses are adequate, however, a follow-up inspection will be required to assure that corrections are in fact adequate. Until it has been determined that corrections are adequate, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts. Additionally, no pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared and no requests for Certificates For Products For Export will be approved.

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You should take prompt action to correct deviations whether identified by our investigator or your internal systems audit. Failure to promptly correct these deviations may result in regulatory action 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 in writing within 15 working days of receipt of this letter, of the anticipated date that your facility will be ready for reinspection. Your response to this letter should be addressed to James Austin Templer, Compliance Officer, at the above letterhead address.

Sincerely,

*Sylvia G. Yett*  
for

Darryl E. Brown  
Acting District Director