



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-24

January 23, 1998

Terence R. Witt, President
Witt Biomedical Corporation
295 North Drive, Ste. H
Melbourne, Florida 32934

Dear Mr. Witt:

We are writing to you because on January 13-15, 1998, FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving cardiac catheterization monitoring systems which are manufactured and distributed by your firm.

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 The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.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 establish and maintain ESD procedures and controls;
- Failure to maintain and implement adequate corrective and preventative action, e.g., not all complaints are treated as complaints, failure reports have not been completed for the third and

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fourth quarters of 1997 as required in your written procedures, and available trending reports are inadequate as to content;

- Failure to establish and maintain adequate procedures for changes to a specification, method, process, or procedure, e.g., software installation procedures are being changed without using an approved process pursuant to established procedures;
- Failure to designate an individual(s) to review the accuracy of all documents established to meet the requirements of the Quality System Regulation, e.g., not all Master Device Records are signed and dated as being approved;
- Failure to establish procedures for identifying training needs and ensuring that all personnel are adequately trained to perform their assigned responsibilities; and
- Failure to follow your own written Internal Audit procedure, e.g., there have not been any audits conducted in the last two years pursuant to your written procedure, which requires audits to be conducted every 6 months.

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 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. You are responsible for investigating and determining the cause of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. 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. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

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You should take prompt action to correct these deviations. 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 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.

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 GMPs and does not necessarily address other obligations you have under the law. You may obtain general information about all the FDA requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800/638-2041 or through the Internet at <http://www.fda.gov>.

Sincerely,



Douglas D. Tolen
Director
Florida District