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Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, Fl 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-64

March 26, 1999

Terrence R. Witt, CEO & President  
Witt Biomedical Corporation  
295 North Drive, #H  
Melbourne, Florida 32934

Dear Mr. Witt:

We are writing to you because on April 13-14, 1999 FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving cardiac catheterization monitoring and recording systems (Class II), 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 that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your 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, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

**GMP REGULATIONS (FDA 483, Item #s1-3)**

- 1) Failure to establish, implement and maintain an adequate complaint handling system, e.g., there are no written procedures and data unrelated to product failures are used to

conduct trend analysis, which confuses and complicates accurate trend analysis [21 CFR 820.198].

- 2) Failure to conduct planned and periodic audits of the quality assurance program including both Design Control and GMP areas, e.g., Design controls, Corrective and Preventive Actions, Purchasing Controls, Change Control, Training, Device Master and History Records, and Installation and Servicing of installed devices [21 CFR 820.22].
- 3) Failure to establish, implement and maintain adequate record keeping procedures, e.g., all parts of the device master record (DMR) are not signed and dated as having been approved [21 CFR 820.181].

**DESIGN CONTROL REGULATIONS (FDA 483, Item #s4 & 5)**

- 1) Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation, as required by 21 CFR 320.30(b), e.g., there was no design plan.
- 2) Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device; and that the design input requirements are documented, reviewed and approved by a designated individual, as required by 21 CFR 820.30(c), e.g., there are no written procedures for design input control nor are there records for the approval of the inputs.
- 3) Failure to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, as required by 21 CFR 820.30(d).
- 4) Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages, as required by 21 CFR 820.30(e), e.g., there are no procedures established that include provisions for formal documented review of the design results at planned appropriate stages; there are no procedures that would indicate that the design review committee includes representatives of all functions concerned with the subject design stage that does not have direct responsibility for the stage being reviewed; and there are no reports from the Design Control Review Committee.

- 5) Failure to establish and maintain procedures for verifying the device design, as required by 21 CFR 820.30(f), e.g., there was no comparison of the outputs to assure the conformance to the inputs.
- 6) Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h), e.g., there are no design transfer procedures; and there are no records of transfers.
- 7) Failure to establish and maintain procedures for the identification, documentation, validation, verification, review, and approval of design changes, as required by 21 CFR 820.30(i), e.g., there were no procedures specific to design control.

The specific violations noted in this letter and in the List of 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. We also note that some of these deficiencies were not corrected from our previous inspection. 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.

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 awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export 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 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 fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the

corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,

A handwritten signature in black ink, reading "Douglas D. Tolen". The signature is written in a cursive style with a large, looping initial "D".

Douglas D. Tolen  
Director, Florida District