



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Admin  
15326

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-1

November 14, 1996

Ref: 97-DAL-WL-4

**WARNING LETTER**

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

Diana McSherry, Ph.D., Chairman of the Board  
and Chief Executive Officer  
Digisonics, Inc.  
2401 Portsmouth  
Houston, Texas 77098

Dear Dr. McSherry:

During an inspection of your firm conducted on May 28, 1996, through June 5, 1996, FDA and Texas Department of Health investigators determined that your firm manufactures and distributes computer software used in conjunction with cardiac diagnostic and fetal growth development systems. The ECHO-COMP System, the Fetal Growth Analysis System and GyneLogic software are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The ECHO-COMP System and the Fetal Growth Analysis System are adulterated within the meaning of section 501(f)(1)(B), in that they are Class III devices under section 513(f) and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for an investigational device exemption under section 520(g).

Further, the ECHO-COMP System is misbranded under section 502(o), in that a notice or other information respecting the modification to the device was not provided to the FDA as required by 21 CFR 807.81(a)(3)(i).

Additionally, the Fetal Growth Analysis System is misbranded under section 502(o), in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by 21 CFR 807.81(a)(3)(ii).

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The inspection also revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. During the inspection of your firm the investigators observed the following deviations:

1. Failure to establish and implement adequate quality assurance procedures that provide detailed descriptions of the procedures to be used to perform regression testing after changes to the software have occurred [21 CFR 820.100(a)(2)].
2. Failure to conduct adequate complaint investigations relative to the reliability, effectiveness or performance of the device [21 CFR 820.198].

For example, ~~of~~ of ~~complaints~~ complaints recorded between July 1995, and May 1996, indicate no investigations were conducted, and no records were maintained that include the reason and the name of the individual responsible for the decision not to investigate these complaints.

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 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 awards of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (section 510(k)'s) will be found to be substantially equivalent for products manufactured at your facility in which the above GMP violations were found until the violations have been corrected.

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You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulator 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.

We acknowledge your response to the FDA-483 dated July 10, 1996. The information in your response is inadequate because it fails to provide sufficient detail of the validation necessary to ensure the device performs as intended. For example, the "Final Device Inspection: Gynelogic Program," is limited input-output testing. There is no assurance the program will operate as intended in the environment or under conditions it was designed. Similarly, the "Operating Procedure for Methodology to Be Used When Performing Regression Testing, June 28, 1996," fails to include all external influences that may impact on the performance of the device. Your procedure is designed only for unit or module testing and does not ensure full integration of the software changes with the existing code.

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 taken to identify and make corrections to any underlying system 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.

Your reply should be directed to the attention of Reynaldo R Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

  
Darryl E. Brown  
Acting District Director

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cc: HFZ-300 (WL Monitor)  
HFZ-332 (FFarrah)  
HFC-210 (CFN: 1626313)  
HFC-240 GWQAP  
HFR-SW150 Deinigner/Aken  
HOU-RP Thorsky/SBrown-LYoung w/CDRH Approval Memo  
HFA-224  
HFI-35 thru CO

TDH/ Tom Brink w/CDRH Approval Memo