



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751

Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA FEDERAL EXPRESS**

**WARNING LETTER**

ORL-99-85

August 19, 1999

Paul M. Shannon, President  
PK Ultrasound  
1750 N. University Dr.  
Suite 202  
Coral Springs, Florida 33071

Dear Mr. Shannon:

We are writing to you because on June 3, 1999, FDA Investigator Mara A. Strier collected information that revealed serious regulatory problems involving the Advanced Technology Laboratories UM4A Ultrasound System. The inspection determined that you promote and use diagnostic ultrasound equipment for the purpose of recording an image of the fetus for keepsake and entertainment purposes, which is a new intended use for the device. The ATL UM4A Ultrasound is a prescription device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act, this product is considered to be a medical device under section 201(h) of the Act because it is used to diagnose a medical condition or to affect the structure or function of the body. During the inspection, the investigator documented violations that cause the device to be adulterated within the meaning of section 501(f)(1)(B) and misbranded within the meaning of section 502(f)(1) and 502(o) of the Act.

**Sections 501(f)(1)(B) and 502(o)**

Because you do not have marketing clearance from FDA, to use the UM4A Ultrasound System for nondiagnostic video taping sessions of the fetus for keepsake videography, and for entertainment purposes, it is in violation of the law. In legal terms, the use of the UM4A Ultrasound System for keepsake videography purposes causes it to be adulterated

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under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. The ultrasound system is adulterated under the Act because the manufacturer of this device did not obtain premarket approval based on information developed by them that shows that this device is safe and effective for this new intended use. The device is misbranded under the Act because the manufacturer did not submit information respecting the new intended use of the ultrasound system to the Food and Drug Administration.

**Section 502(f)(1)**

Additionally, the device is further misbranded under section 502(f)(1) of the Act because the ultrasound system must be used on the prescription or other order of a licensed physician in the course of his or her professional practice. If the ultrasound system is not used in accordance with the law, because it is a prescription device, it lacks adequate directions for use.

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.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections. If you decide to sell or otherwise dispose of the device, it is your responsibility to assure that it is sold only to persons who deal in the sale of such devices, or to persons who are qualified and licensed to use it.

Please direct your reply to the attention of Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

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Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's 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

cc: Advanced Technology Laboratories  
22100 Bothell Highway, S.E.  
Bothell, WA 98041