



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d1452b

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-64

August 7, 1998

Dr. John R. Postlewaite, D.C.
President/owner
VF Works, Inc.
4159-A Corporate Ct.
Palm Harbor, Florida 34683

Dear Dr. Postlewaite:

We are writing to you because on April 20 and May 5-7, 1998, FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving the Visualizer 2000 videofluoroscopy system (Class II), which is manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (The Act), this product is considered to be a medical device under section 201(h) of the Act because it is 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 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 The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.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 Visualizer 2000 or VF 2001 is 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 requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

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- Failure to have in place an adequate organizational structure and sufficient personnel to assure devices are manufactured in accordance with the QS regulation and to establish a formal Quality Assurance program including the establishment of written procedures that address management responsibility, quality audits, personnel, training, design controls, corrective and preventive action, and nonconforming product review.
- Failure to assure that finished devices meet all specifications prior to distribution, e.g., there is no documentation of finished device testing for 4 of 11 stationary devices and 11 of 33 mobile units completed since December 1994.
- Failure to establish a complaint handling system.
- Failure to adequately document procedures and activities covering the manufacturing and quality assurance of the Visualizer 2000 including Device Master Records (DMR), Device History Records (DHR) and Quality System records.

The Visualizer 2000 is also misbranded within the meaning of 502(t)(2) in that there was a failure or refusal to furnish any material or information required by or under section 519 respecting the device, e.g., failure to have a MDR procedure.

You should know that these are serious violations of the law that 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. 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, distribution and quality assurance systems. 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. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Suite 200, Orlando, Florida 32751.

Dr. John R. Postlewaite, D.C.

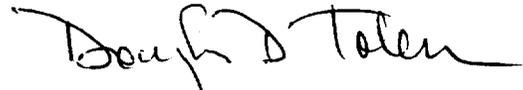
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Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is fluid and cursive, with the first name being the most prominent.

Douglas D. Tolen
Director, Florida District