



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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January 20, 2000

WARNING LETTER

NWE-18-00W

VIA FEDERAL EXPRESS

Jack E. Price, President and Chief Executive Officer
Philips Medical Systems No. America
710 Bridgeport Avenue
Shelton, CT 06484

Dear Mr. Price:

During an inspection of your firm located in Shelton, CT on October 18-21, 27, 28, and November 4, 1999, Investigators Edward Janik and Stephen Souza determined that your firm imports the Tomoscan M/EG, Tomoscan SR4000, Diagnost OP, BV 26 and Angio Diagnost systems. These systems are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that the x-ray and CAT systems identified above are misbranded under section 502(t)(2) of the Act, in that you failed to furnish material or information required by, or under, section 519 respecting your devices. Specifically, you failed to submit written reports to FDA of corrections or removals, as required by 21 CFR 806.10. For example,

Tomoscan M/EG

In September, 1999, your firm implemented Field Change Orders (FCO's) 20703028 and 20703029 in response to information that a mechanical switch designed to control the table movement of this device failed on two systems installed in Germany. This failure caused two (2) patients to absorb all of the x-ray volume they were receiving in one anatomical location. Despite the fact that you initiated and implemented two (2) FCO's in response to these events, the corrections you undertook were not reported to the Agency.

BV 26

On September 18, 1999, your firm implemented FCO 10387011 in response to information that the welding of the wheel plates on this device may fail. Furthermore, a Medical Device Report (MDR 1217116-1999-00008) was filed as a result of an injury sustained by an x-ray technologist due to this failure. Despite the fact that you initiated and implemented an FCO in response to this event, the correction you undertook was not reported to the Agency.

Tomoscan SR4000

On April 3, 1999, your firm implemented FCO 16703028 in response to information that the image may be reversed with respect to right/left orientation when this device is used in "head/top view" mode. Despite the fact that you initiated and implemented an FCO in response to this event, the correction you undertook was not reported to the Agency.

Diagnost OP-C9

On February 16, 1999, your firm implemented FCO 01384002 in response to information that the bolts securing the C-arm of this device to its upper support could become loose. Despite the fact that you initiated and implemented an FCO in response to this event, the correction you undertook was not reported to the Agency.

Angio Diagnost

On January 21, 1998, your firm implemented FCO 00359002 after receiving information that patients could fall off the table of this device due to the unexpected movement and rotation of the tabletop and/or table base. Furthermore, MDR Nos. 1217116-1999-0003 and 1217116-1999-0006 were filed after two patients fell off the table during procedures using this device. We note that your service technicians apparently made additional corrections to this device in February and March 1999, after the receipt of the medical device reportable events which led to the filing of the MDR's. These corrections were not reported to the Agency.

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. 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without

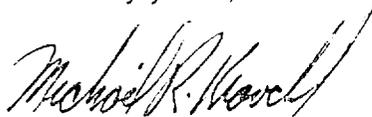
further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of 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.

We acknowledge the receipt of Mr. Peter Altman's letter dated November 8, 1999. However, we still require a detailed response from you informing us how you intend to correct the violations noted in this letter, and the steps you have undertaken to prevent their recurrence. For your information, a copy of the document entitled, "Medical Devices: Reports of Corrections and Removals Guidance" is enclosed for reference.

Your reply should be directed to Alyson L. Saben, Compliance Officer, U.S. Food & Drug Administration, New England District Office, One Montvale Avenue, Stoneham, MA 02180.

Sincerely yours,



Michael R. Kravchuk
Acting District Director
New England District Office

Enclosure