



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 16, 2003

VIA CERTIFIED MAIL

In reply refer to Warning Letter SEA 04-02

Randy Dobbs, President and CEO
Philips Medical Systems Region North America
22100 Bothell-Everett Highway
Bothell, Washington 98021-8431

WARNING LETTER

Dear Mr. Dobbs:

We are writing to you because during an inspection from June 16 through June 24, 2003, the Food and Drug Administration (FDA) became aware of information that revealed a serious regulatory problem involving the following products:

Easy Web (FCO# 83000001) classified as a Class II recall under recall #Z-1128-3;

Diagnost 94 (FCO# 00280011) classified as a Class II recall under recall #Z-1203-3;

Diagnost 96 (FCO#00278023) classified as a Class II recall under recall # Z-1204-3;

Diagnost 97 (FCO#00281009) classified as a Class II recall under recall #Z-1205-3;

Gyroscan ACS-NT (FCO#07800003) classified as a Class II recall under recall #Z-1199-3;

Gyroscan NT-Intera 1.5T (FCO#07800003) classified as a Class II recall under recall #Z-1200-3;

Gyroscan 1.5T Intera (FCO#07800003) classified as a Class II recall under recall #Z-1201-3;

Gyroscan ACS-NT (FCO#78100006) classified as a Class II recall under recall #Z-1227-3;

Gyroscan NT-Intera (FCO#78100006) classified as a Class II recall under recall #Z-1228-3;

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Gyroscan Intera 1.0T & 1.5T (FCO#78100006) classified as a Class II recall under recall #Z-1229-3;

EasyAccess PACS System w/software 5, 6.2, or 7.2 classified as a Class II recall under recall #Z-0471-3.

As the US Agent responsible for initial handling of complaints, submission of Medical Devices Reports, 501(k) or PMA submissions, Submissions of Corrections and Removals, and Radiological Product Reports, your firm is responsible for these violations.

Your Easy Web, Diagnost 94, Diagnost 96, Diagnost 97, Gyroscan ACS-NT, Gyroscan NT-Intera 1.5T, Gyroscan 1.5T Intera, Gyroscan ACS-NT, Gyroscan NT-Intera, Gyroscan Intera 1.0T & 1.5T, and your *EasyAccess PACS System w/software 5, 6.2, or 7.2* devices are misbranded within the meaning of Section 502(t)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) in that a report of correction or removal was not submitted to FDA as required by Section 519(f)(1) of the Act. The Correction and Removal Regulation (21 CFR 806), promulgated under Section 519(f)(1), requires manufacturers and importers to promptly report to FDA, within 10 working days, any correction or removal of a device to reduce a risk to health.

As FDA informed you by letters dated August 20, 2003, and September 16, 2003, FDA has classified your actions regarding the Easy Web, Diagnost 94, Diagnost 96, Diagnost 97, Gyroscan ACS-NT-Intera, Gyroscan NT-Intera 1.5T, Gyroscan 1.5T Intera, Gyroscan ACS-NT, Gyroscan NT-Intera, Gyroscan Intera 1.0T & 1.5T, and your *EasyAccess PACS System w/software 5, 6.2, or 7 products* as Class II recalls. A Class II designation indicates that exposure to the violative product may cause temporary adverse health consequences. See 21 CFR 7.3(m). FDA regulations require manufacturers and importers to promptly report to FDA any correction or removal of a device if the correction or removal was initiated to reduce a risk to health. See 21 CFR 806.10 (a)(1). Because your firm's action described above meets the definition of a "removal" in 21 CFR 806.2(i) and because FDA has found that the removal was initiated to reduce a risk to health, your failure to report the product removal until the issue was raised by our investigator violated 21 CFR 806.10(a)(1).

You should take prompt action to correct this violation and prevent its reoccurrence in the future. Failure to promptly correct these violations may result in FDA initiating regulatory action without further notice. 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 they may consider this information when awarding government contracts.

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Please notify us 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 correction. Send your written reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson, Compliance Officer, at (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director