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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER**VIA FEDERAL EXPRESS**

AUG - 8 2003

Jouko Karvinen
Chief Executive Officer
Philips Medical Systems, Inc.
3000 Minuteman Road
Andover, Massachusetts 01810

Re: K963990, K980645, K992533,
K001796, K013344

Dear Mr. Karvinen:

We refer to promotional information appearing on Philips Medical Systems, Inc.'s (Philips') website, <http://www.medical.philips.com/>, regarding the magnetic resonance (MR) imaging devices cleared under the above-referenced 510(k)s and currently marketed by your firm under the "Intera" trade name. This information is false or misleading, in that it impliedly claims that these devices have been cleared or approved by FDA for use with contrast agents in cardiac perfusion.

At the [main/products/interafamily/intera-it/cv](#) link from your company's home page, we found pictures and discussion of the use of the Intera I/T for "localized contrast media delivery." The link from the home page at [main/products/mri/products/interafamily](#) says that the Intera CV may be used for "Cardiac function and perfusion analysis." And at the [main/products/mri/applications/cardiology/perfusion](#) link of your company's home page, it states that the Intera CV may be used by cardiologists for perfusion imaging: "Intera eliminates guesswork and enables you to base treatment decisions on firm knowledge. Ultra-fast, multislice, multi-dynamic perfusion studies can be completed in minutes without radioactive isotopes. The results have been shown to be as good as, if not better than, nuclear medicine studies." Promotional statements recommending or suggesting these devices for cardiac perfusion also appear in a "commercial brochure" entitled "Cardiovascular MR: the Intera advantage," which was submitted to FDA by Mr. Peter Altman, Director, Regulatory Affairs, on August 15, 2001. The brochure states that "[t]he Intera CV is a dedicated cardiovascular MR scanner that will enable you in a single examination to ... assess cardiac perfusion" and is replete with references to perfusion studies and use of contrast media.

These claims imply that your devices have been cleared or approved for use in cardiac perfusion studies with contrast agents. Philips has not been granted clearance or approval from FDA for use of these devices for cardiac perfusion, and there are currently no contrast agents approved for use in imaging of the heart in the United States. The

intended use for which these devices were cleared by the Office of Device Evaluation is as follows: “Indicated for use as diagnostic devices that produce transverse, sagittal, coronal, oblique cross-sectional images, spectroscopic images and/or spectra, based upon ¹H and ³¹P metabolites, and that display the internal structure of the head, body, or extremities.”

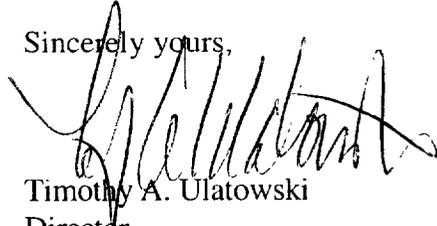
Labeling that claims, either expressly or by implication, that FDA has approved or cleared a medical device for an intended use when the agency has not granted approval or clearance for that use make a device misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 352(a). Moreover, labeling for a device that claims that FDA has approved a contrast agent for use in cardiac perfusion when, in fact, FDA has not granted such approval, is false or misleading under the Act. 21 CFR 801.6. Claims recommending or suggesting use of a device that is different from the use for which FDA has granted clearance or approval create a new “intended use” for which adequate directions must be provided in labeling. 21 U.S.C. § 352(f)(1). Absent such directions, a device is misbranded under section 502(f)(1) of the Act.

We acknowledge the letter sent by Mr. Altman to Ms. Deborah Wolf dated August 15, 2001. Mr. Altman’s letter was in response to our letter dated April 4, 2001, in which we advised Philips that these devices were not cleared for cardiac perfusion. Mr. Altman stated that K992533 included pages for cardiac perfusion imaging. Although pages 25 and 26 of Appendix I.b. of the 510(k) stated that “[t]he Cardiac Perfusion Package enables multi-slice first pass cardiac perfusion studies for assessment of cardiac perfusion in rest and stress situations,” the mere fact that Philips referenced and/or discussed cardiac imaging in its 510(k) does not mean that the agency cleared the devices for that use.

You should take prompt action to correct these violations. 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 prevent the recurrence of similar violations. 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. Please direct your response to Mr. Steven E. Budabin, M.S., Consumer Safety Officer, Cardiovascular and Neurological Devices Branch, at the letterhead address. Failure to promptly correct these violations 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 money penalties. Also, 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.

This letter is not intended to be an all-inclusive list of deficiencies associated with your devices. It is your responsibility to ensure adherence to each applicable requirement of the Act and regulations for every FDA-regulated product that you market. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Timothy A. Ulatowski', written over the printed name.

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health