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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2003

Kristen K. Hughes, Esq.
SG&A Consulting, Inc.
1701 E. Lamar Blvd., Suite 160
Arlington, TX 76006

Dear Ms. Hughes,

This is in response to your request for an advisory opinion dated August 12, 2002 asking for information on the classification of, and resulting manufacturer responsibility for, data and image archiving technology. We apologize for the delay in responding to your letter. However, your request was inadvertently forward to the Center for Drug Evaluation and Research (CDER).

After reviewing your request for an advisory opinion, we have concluded that your request should be handled as a request under section 513(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360c(g) (the Act)): As stated in section 513(g) of the Act, we will respond to your request for information regarding the class in which a device has been classified or the requirements applicable to a device under the Act, within 60 days of designation of your petition as a section 513(g) request.

We have now forwarded your request to the Office of Device Evaluation for processing. If you have any questions about this response, please call Jake Romanell, 513(g) Coordinator, at (301) 594-1190, or Joseph M. Sheehan, Director of the Regulations Staff, at (301) 827-2974.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health

02A-0379

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