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January 28, 2005

Mr. Tom Mosley  
Diagnostic Devices Branch (HFZ-322)  
Division of Enforcement I  
Office of Compliance  
Center for Devices and Radiological Health  
Food and Drug Administration  
2098 Gaither Road  
Rockville, MD 20850

**Re: Request for Extension of Variance No. 84V-0380**  
**Current Termination Date: April 12, 2005**

Dear Mr. Mosely,

We hereby request a five-year extension of our current variance from the requirements of 1020.32(h)(2) of the Performance Standards for Radiographic Equipment (21 CFR 1020.31) and the requirements of 1020.32(f) of the Performance Standard for Fluoroscopic Equipment (21 CFR 1020.32).

The current variance bears FDA Docket No. 84V-0380. All of the conditions of this variance remain the same.

Sincerely,

*Anastasia C. Randall*

Anastasia C. Randall  
Senior Regulatory Affairs Specialist  
Hologic, Inc.

**84V-0380**

**EXP 3**