

# DIGITEC MEDICAL SERVICE CORPORATION

2041 '00 MAR -1 P1:41

February 24, 2000

Docket No 990-4910  
Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

21 CFR 900.12 (b)(8)(i)

Enclosed are our comments relating to 21 CFR 900.12(b)(8)(i) and the GE 500T/600T mammography systems. Please be advised that my company, Digitec Medical Service Corporation, has recently received 510(k) clearance to market a modification for the 500T/600T systems. We developed the modification because we believe the original design of the 500T/600T systems does not meet the standard.

This is why we believe it does not:

- When the operator activates the down foot pedal, there is a time delay before the compression paddle begins to move.
- This time delay is encountered everytime the pedal is activated. "Quick tapping" of the foot control will not smoothly add compression force.
- To add incremental force, the operator must activate the down pedal, wait for the time delay, anticipate the end of the delay, gauge the amount of force added, and then quickly release the control.

As the intent of the regulation is to provide predictable, controlled incremental adjustment, we do not believe the original design meets the regulations.

Thank you for allowing us to present our comments.

Regards,



James McGinty

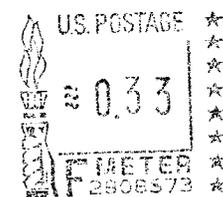
JJM:jem

990-4910

C 4

**DIGITEC MEDICAL SERVICE CORPORATION**

465 Maltbie Street, Suite 407  
Lawrenceville, GA 30045



Docket No 990-4910  
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

20857-0001

