



**SOUTH ORLANDO OB-GYN GROUP
DIAGNOSTIC CENTER**

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March 1, 2000

Docket No. 99D-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

RE: CFR 900.12(b)(8)(i)

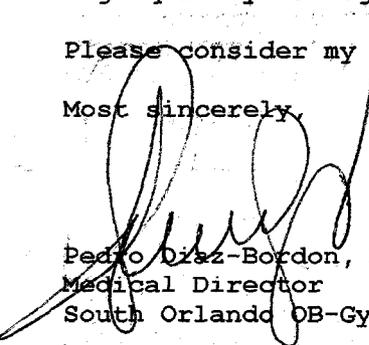
To Whom it May Concern:

I would like to speak against the requirement for the fine adjustment compression controls operable from both sides of the patient.

I feel this is an onerous requirement since our current unit, the GE600T, would otherwise comply with FDA regulations but would have to be removed from service, since at this time there are no upgrades available that would make this unit within compliance. Replacing this unit would require an expense of approximately \$80,000. I truly believe that this cost is not justified for such a questionable benefit. This could drive some privately owned breast imaging centers, including our own, out of business. This would decrease access to high-quality mammograms, which seems contrary to the goal of the MQSA.

Please consider my comments in drafting the final regulation.

Most sincerely,


Pedro Diaz-Bordon, M.D.
Medical Director
South Orlando OB-Gyn Group Diagnostic Center

99D-4910

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