



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 20, 2000

Ted L. Parrot
GE Medical Systems OEC
384 Wright Brothers Drive
Salt Lake City, UT 84116

Dear Mr. Parrot:

Your variance requesting the Food and Drug Administration to approve a source-skin distance requirement of the performance standard for fluoroscopic equipment, as it applies to the Mini 6800 Mobile C-arm was received by this office on 04/20/00. It was assigned docket number 00V-1264/VAR1 and it was filed on 04/20/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Helen K. Harris".

Helen K. Harris
Dockets Management Branch