



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

October 13, 2005

Mr. Larry S. Grossman
OrthoScan, Inc.
8585 E. Hartford Drive
Suite 900
Scottsdale, AZ 85255

FILE COPY

Dear Mr. Grossman:

Your petition requesting the Food and Drug Administration to grant a variance from the source-skin distance requirement of the performance standard for fluoroscopic equipment, was received by this office on 10/11/2005. It was assigned docket number 2005V-0415/VAR1 and it was filed on 10/13/2005. 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,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005V-0415

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