

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
1350 PICCARD DRIVE
ROCKVILLE, MD 20850

November 14, 2007

Reference: 0710836-000

Ray Manez
Director, Operations
SOURCE-RAY, INC.
167 KEYLAND CT.
BOHEMIA, NY 11716

This is to acknowledge receipt of your November 2, 2007, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (title 21, code of Federal Regulations, Subchapter J) as they pertain to Initial Product Report.

Your document has been assigned an accession number of 0710836-000, and has been classified as a(n) Initial Product Report (pursuant to Part1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Initial Product Report. These Medical Diagnostic X-Ray Equipment include designated model family(s) X-Ray Source Assembly with model(s) SB-125-7K-P".

This acknowledgement does not constitute approval of the document. You will be contacted if any questions or comments arise concerning your document.

Thank you for your cooperation. If you have questions or comments, please write to the address above or call (240) 276-3332.

Sincerely Yours,

CAPT Thomas Jakub
Diagnostic Devices Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs