DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
10903 New Hampshire Avenue
WO66-4617
Silver Spring, MD 20993

September 2, 2010

Reference: 1010417-000

Raymond Manez
Offical Correspondent
SOURCE-RAY, INC.
167 KEYLAND CT.
BOHEMIA, NY 11716

This is to acknowledge receipt of your August 31, 2010, 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 requirements.

Your document has been assigned an accession number of 1010417-000, and has been classified as a(n) Initial Product Report (pursuant to Part 1002, 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 Portable X-Ray System with model(s) PowerMax 1260.".

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

Please note that your firm is required to submit an Annual Report to CDRH every year by September 1.

All Radiological Reports may be prepared using FDA's Electronic Submissions software which can be downloaded at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm. For more information on the FDA's eSubmitter program please see the following websites:

Radiological Health - http://www.fda.gov/Radiation-EmittingProducts/default.htm

Electronic Submissions (instead of paper reports) -
http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

FDA Electronic Submissions Gateway -
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

Thank you for your cooperation. If any questions or concerns arise during our review of your report, we will notify you. If you have any questions, contact us at (301) 796-5710.

Sincerely Yours,

Sean M. Boyd
Diagnostic Devices Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs
http://www.fda.gov/Radiation-EmittingProducts/default.htm