FOOD AND DRUG ADMINISTRATION CENTER FOR DEVICES AND RADIOLOGICAL HEALTH 2098 GAITHER ROAD ROCKVILLE, MD 20850

APRIL 19, 2004

REFERENCE: 0410554 = 00

RAYMOND MANEZ DIRECTOR, OPERATIONS SOURCE-RAY INC. 167 KEYLAND CT BOHEMIA, NY 11716

This is to acknowledge receipt of your APRIL 15, 2004, 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 medical diagnostic x-ray equipment.

YOUR DOCUMENT HAS BEEN ASSIGNED AN ACCESSION NUMBER OF 0410554, AND HAS BEEN CLASSIFIED AS a product report (initial), (pursuant to Section 1002.10 of the Regulations referenced above).

Further, the submittal has been assigned an informal subject title of "PRODUCT REPORT (INITIAL) ON MEDICAL DIAGNOSTIC X-RAY: FOR THE FLUOROSCOPIC X-RAY GENERATOR, MODEL SR-1003KF."

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 (301) 594-4591.

THOMAS M. JAKUB, CHIEF DIAGNOSTIC DEVICES BRANCH DIVISION OF ENFORCEMENT B OFFICE OF COMPLIANCE