

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH  
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This is to acknowledge receipt of your June 18, 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 1010312-000, 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 Utility/Peripheral Laser Products include designated model family Scanner with model(s) RealScan-F".

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,

Robert J. Doyle  
Electronic Products Branch  
Division of Mammography Quality and Radiation Programs  
Office of Communication, Education, and Radiation Programs  
<http://www.fda.gov/Radiation-EmittingProducts/default.htm>