DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

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

OCTOBER 19, 2005

REFERENCE:
0522451-00

GWANG BAE KIM
QUALITY CONTROL TEAM MANAGER
TERADIAN INC.
946 DUNSAN-DONG,
SEO-GU, DAEJEON, 302-120,
KOREA

This is to acknowledge receipt of your OCTOBER 7, 2005, 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 laser products (except medical devices).

YOUR DOCUMENT HAS BEEN ASSIGNED AN ACCESSION NUMBER OF 0522451, AND HAS BEEN CLASSIFIED AS a product report (model change), (pursuant to Section 1002.12 of the Regulations referenced above).

Further, the submittal has been assigned an informal subject title of "PRODUCT REPORT (MODEL CHANGE) ON LASER PRODUCTS (NON-MEDICAL): FOR THE LASER DIODE COMPONENT, MODELS TLF, TLD, TAF, TAD, TBF, TBD, TWF, TWD, TMF AND TMD."

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) 594-3332.

Sean M. Boyd
CHIEF, ELECTRONIC PRODUCTS BRANCH
DIVISION OF MAMMOGRAPHY QUALITY AND
RADIATION PROGRAMS
OFFICE OF COMMUNICATION, EDUCATION, AND
RADIATION PROGRAMS