

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

May 19, 2009

Reference: 0910213-000

Steve Liu

This is to acknowledge receipt of your May 4, 2009, 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 0910213-000, 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 Other Laser Products include designated model family Wicked Lasers (Class 3B DPSS) with model(s) Executive, Evolution, Elite and Pulsar."

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 on September 1. This report may be prepared using CDRH's electronic submissions software, which can be downloaded at www.fda.gov/cdrh/cesub. You may also submit a paper Annual report, available online at www.fda.gov/cdrh/radhealth.

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

Sincerely Yours,

Robert Doyle
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs