

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

JANUARY 5, 2005

REFERENCE:
9522059-05

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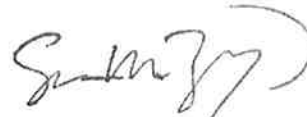
This is to acknowledge receipt of your DECEMBER 27, 2004, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (Title 21, Code of Federal Regulations, Subchapter J) AS they pertain to laser products (except medical devices).

Your document has been classified as supplement 05 to accession number 9522059, which is 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 "SUBMITTING CLASSIFICATION CHANGES FOR THE S18 PRODUCT FAMILY, FROM CLASS 2 LASER TO CLASS 1 LASER."

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 (240) 276-0326



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