



DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA/DMB HFA-305

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 5:43 '99 JAN 13 P2:17

Ref: FDA Docket No. 99V-4065

Accession No. 99A2344

Mr. Kin Wong
Quality Assurance Manager
FLIR Systems Boston
16 Esquire Road
Billerica, Massachusetts 01862

Dear Mr. Wong:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of FLIR Systems Boston, dated September 3, 1999, for a variance from 21 CFR 1040.10(e)(3)(i) of the performance standard for laser products is approved for the MARFLIR laser rangefinder. This variance will allow the introduction into commerce of the laser product described in paragraph D below.

A. Variance Number

99V-4065

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated 5 years from the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for the MARFLIR laser rangefinder for sale to the U.S. Department of Defense and other government agencies.

E. Provision from Which Variance is Granted

This variance is granted from 21 CFR 1040.10(e)(3)(i) of the performance standard for laser products requiring that the determination of the level radiant energy laser or power for the purpose of classification shall be made using a 50 mm diameter aperture for products intended to be used in locales where the emitted laser radiation is likely to be viewed with optical instruments.

F. Conditions under Which Variance is Granted

In lieu of the requirement referred to in Item E above, the conditions as specified below shall apply to the products and devices manufactured under this variance:

99V-4065

VRA 1

1. Classification of the product shall be performed in accordance with the provisions of the American National Standard for the Safe Use of Lasers, ANSI Z136.1 1993 or the latest revision thereof.
2. Sales shall be direct by purchase order to the procuring government agencies, and not through warehouse stock of distributors.

G. Basis for Approval of Variance

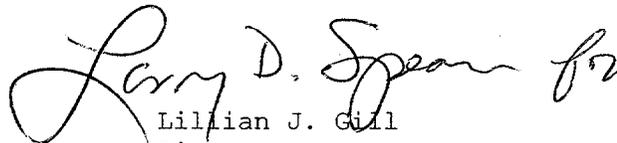
In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design. The referenced ANSI standard upon which this approval is based utilizes more up-to-date biophysical and physical knowledge and recognizes that the wavelength of the emission is beyond what is accepted to be the retinal hazard range.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state: This product complies with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 99V-4065 effective

This variance action is available for public disclosure in the Food and Drug Administration (FDA) Dockets Management Branch and a notice of availability will be published in the Federal Register. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 99V-4065