



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA/DMB - HFA-305

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ref: FDA Docket No. 94V-0448
Accession No. 94A1001

Mr. Ed Reynolds
Vice President
Laser Products
18300 Mt. Baldy Circle
Fountain Valley, California 92708-6117

Dear Mr. Reynolds:

In accordance with 21 CFR 1010.4(c)(1), I am approving the petition of Laser Products, dated December 2, 1999, for a renewal of their variance, Number 94V-0448, from the requirements of 21 CFR 1040.10(f)(3), 1040.10(f)(4), 1040.10(f)(5) and 1040.10(f)(6) of the performance standard for laser products. This variance, under the conditions stated below, will allow the introduction into commerce of the Class IIIb, 5 mW, Sure-Fire infrared laser sight module, model L75 manufactured by Laser Products.

A. Variance Number

94V-0448

B. Effective Date

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

C. Termination Date

This variance shall be terminated on January 13, 2005.

D. Laser Product for Which Variance is Granted

This variance is granted for the Class IIIb, 5 mW, Sure-Fire laser sight module, model L75.

E. Provisions From Which Variance is Granted

This variance is granted from the provisions of 21 CFR 1040.10(f)(3), 1040.10(f)(4), 1040.10(f)(5), 1040.10(f)(6) and from 1040.11(b) that require that each Class IIIb laser system incorporate a remote interlock connector, a key control, an emission indicator and beam attenuator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I. Under the terms of

94V-0448

VRA2

this variance the product will not incorporate the specified performance features although alternate means (normally off, momentary power switch and battery removal) shall be employed in place of these performance features.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions Under Which Variance is Granted

In lieu of the requirement referred to in Item E above, the following conditions shall apply to the Class IIIb, 5 mW, Sure-Fire laser sight module, model L75 manufactured under this variance.

1. The sales of the infrared laser sight shall be restricted to government, military and law enforcement agencies under direct purchase order and shall not be sold to individual law enforcement personnel.
2. The user information to be supplied with each laser sight module shall include:
 - a. Detailed written instructions on the radiation hazards of the laser sight module and on its safe use including warnings against ocular hazard distance while being used in a training program.
 - b. A statement that resale of these products is restricted to government, military, or law enforcement agencies under direct purchase order.
 - c. A statement that the batteries shall be removed when the product is not intended to operate to prevent unauthorized use.
 - d. A statement that the product is to be used only with night vision equipment that attenuates the laser radiation to Class I levels through the optics.
 - e. A statement that the illuminators are not to be used with true retro-reflectors.
3. Each laser sight module shall incorporate a normally-off, momentary power switch to prevent emission of laser radiation when laser emission is not required.

G. Basis for Approval of Variance

The Center for Device and Radiological Health has determined, in accordance with 21 CFR 1010.4(a), that the laser products utilize alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard. In context of the design and nature of this product, warnings regarding possible hazards resulting from radiation exposure, the instructions advising the user to remove the batteries to avoid inadvertent exposure and the normally off, momentary power switch that must be continuously depressed by the operator in

order for the product to function are believed to constitute equivalent means of providing the radiation safety as would be provided by a remote interlock connector, key switch, emission indicator, and beam attenuator. This variance also recognizes that the infrared emission is necessary for covert operations of military and police operators.

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 is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 94V-0448 effective January 13, 1995."

This variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,



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

Drafted:MKaros:01/12/2000
Reviewed:LDSmith:01/13/2000
Final:lsg:02/02/2000

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CR 2/7/00
lsg 2/9/00
WDS 2/3/2000

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CC: Karos
Smith
EPB Board
Variance Book
LOS-DO (HFR-PA250)
RRHR-PA (HFR-PA39)
Zaharek (HFR-PA1530)
FDA/DMB (HFA-305) (Docket No. 94V-0448)
DE3 (CF, FF, RF)
HFA-224