



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA/DDM HFF-305

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

AUG 11 2004

Ref: FDA Docket No. 02V-0283
Accession No. 02A1219-01

Mr. Coy Comart
President
International Laser and Light, Inc.
1984 Water Ridge Drive
Fort Lauderdale, Florida 33326

Dear Mr. Comart:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of International Laser and Light, Inc., dated July 28, 2004, for a renewal of their variance, Number 02V-0283, from 21 CFR 1040.11(c) of the performance standard for laser products is approved. This variance will allow the introduction into commerce of the laser light show products described in paragraph D below.

A. Variance Number

02V-0283

B. Effective Date

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

C. Termination Date

This variance shall be terminated after August 22, 2007.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb or IV laser light shows assembled and produced by International Laser and Light, Inc. The shows will incorporate a certified Cosmic Ray VIII laser projection system which may contain helium-neon, krypton, argon, argon/krypton, or frequency-doubled Nd:YAG lasers.

The firm's laser light shows will be presented in any type of facility or outdoor, unenclosed area for any contracted duration. The shows may employ front or rear screen projections, multiple reflection/diffraction effects, reflections from stationary mirrors, stationary or scanning irradiation of rotating mirror balls, fiber optic projections, and enhanced scattering effects.

E. Provision from Which Variance is Granted

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products requiring that each demonstration laser product shall comply with all of the applicable requirements of

02V-0283

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21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in Item E above, the conditions as specified below in Variance Attachment A and Variance Attachment B shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

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, and by warnings in the user/purchaser information.

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 02V-0283 effective August 22, 2002.

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,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 02V-0283

Attachments A and B