



AUG 9 2004

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

Ref: FDA Docket No. 2003V-0484
Accession No. 04A0532

Mr. Ivan Kostadinov
Manager
Pulslight Co.
72 Blvd Tzargradsko Chausee
1784 Sofia
Bulgaria

Dear Mr. Kostadinov:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Pulslight Co., received April 13, 2004, for a variance 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

2003V-0484

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 two (2) years from the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for the Class IV laser light shows assembled and produced by Pulslight Co. The shows will incorporate a certified Pulslight Co. Yellow Raptor 05 laser projection system containing certified copper bromide laser emitting at 510-578 nm. The projection system is intended for sale in the United States through Grace Audio Technologies, Inc., 45225 Tioga Street, Temecula, California 92592.

The shows will be presented at a variety of locations for any contracted duration. The shows may employ front or rear screen projections, holographic displays, 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

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product shall comply with all of the applicable requirements of 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 2003V-0484 effective AUG 9 2004 .

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 Division of Dockets Management, Docket No. 2003V-0484

Attachments A and B