



DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA/CDRH HEP-305  
Public Health Service

SEP 30 2004

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

Ref: FDA Docket No. 99V-1390  
Accession No. 99A0098-01

Mr. William R. Benner, Jr.  
President  
Pangolin Laser Systems, Inc.  
771 South Kirkman Road, #113  
Orlando, Florida 32811

Dear Mr. Benner:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Pangolin Laser Systems, Inc., dated August 24, 2004, for renewal of 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

99V-1390

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 June 15, 2007.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb Pangolin Signature 300 laser projector and laser light shows (Pangolin Shows A, B, and C) assembled and produced by the firm incorporating the Signature 300 projector. The Signature 300 projector incorporates a certified argon/krypton ion laser.

The laser light shows may be presented in permanent or temporary installations in any type of facility or outdoor unenclosed area for any contracted duration. The effects employed may be front or rear screen projections, multiple reflection/diffraction effects, reflections from stationary mirrors, 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 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall

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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**

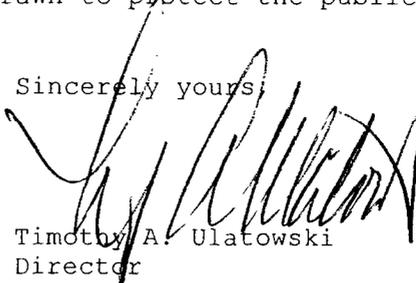
In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety 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 99V-1390 effective June 15, 1999.

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. 99V-1390

Attachments A and B