



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 16 2005

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Food and Drug Administration
Center for Devices and
Radiological Health
2025 Garfield Road
Rockville, MD 20850

Ref: FDA Docket No. 99V-0555
Accession No. 99A0334-02

Mr. Bruce Brazell
Planetarium Director, Navarro College
Cook Arts, Science, and Technology Center
3100 West Collin Avenue
Corsicana, Texas 75110

Dear Mr. Brazell:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Cook Arts, Science & Technology Center of Navarro College, dated February 16, 2005, for a renewal of their variance, Number 99V-0555, 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-0555

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 May 17, 2008.

D. Product for Which Variance is Granted

This variance is granted for the Class IV laser displays assembled and produced by Cook Arts, Science, and Technology Center. The laser displays will be produced with a certified Laser Images Model Dual RGB laser projection system containing a certified argon/krypton laser.

The displays will be presented from a permanent installation in Cook Arts, Science & Technology Center's planetarium. The shows may employ front screen projections, multiple reflection/diffraction effects, 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 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.

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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

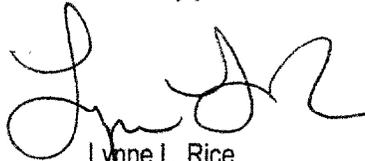
In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety 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-0555 effective May 17, 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,



Lynne L. Rice
Director
Office of Communication, Education,
and Radiation Programs
Center for Devices and Radiological Health

cc: FDA Division of Dockets Management, Docket No. 99V-0555

Attachments A and B