VIA Email

January 31, 2022

Joel Finley
Epson America, INC.
3131 Katella Avenue,
Los Alamitos, Califoria 90720

Re: FDA Docket Number: FDA-2022-V-0103
Accession Number: 22A0752

Dear Joel Finley:

The Center for Devices and Radiological Health (CDRH) is approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Epson America, INC., ("the firm") dated December 22, 2021, for a variance from 21 CFR 1040.11(c) of the performance standard for laser products.

This variance will allow the introduction into commerce of the laser light show products described in Section D below.

A. Variance Number

2022-V-0103

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 December 31, 2022, unless extended by the submission of an annual report, as required by 21 CFR 1002.13. Only upon submission of an annual report, this variance shall be extended for one year at a time, effective December 31 each year.

D. Product(s) for Which Variance is Granted

This variance is granted for the Laser Class IIIb, Laser Class IV, and/or Risk Group (RG) 3 laser light shows manufactured by the firm that incorporate any of the following certified Laser Illuminator Projectors (LIPs): model(s) EB-PU2120W, EB-PU2220B projectors.

The firm may manufacture, report and certify Laser Class IIIb, Laser Class IV, and/or RG3 LIPs under this variance. The firm may also incorporate into its laser light shows any LIPs which have been certified and reported by the firm or by another LIP manufacturer under an approved laser light show variance, except:

1. Projection systems designed or intended to produce visible effects by means of invisible laser emissions, or

2. Projection systems designed for producing effects other than front or rear screen projections.

The firm's laser light shows may be presented in temporary or permanent installations in any type of facility or outdoor space. RG3 LIPs may only be used to create front or rear screen projection effects. RG3 LIPs are not designed or intended for home use.

E. Provisions From Which Variance is Granted

This variance is granted from the portion of 21 CFR 1040.11(c) of the performance standard for laser products which requires that each demonstration laser product shall not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa.

All other provisions of the applicable performance standard(s) remain applicable to the product.

F. Conditions Under Which Variance is Granted

In lieu of the requirement(s) referred to in Item E above, the conditions as specified below in Variance Attachment A.3.1 shall apply to the laser light 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 Section E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, installation requirements, and by warnings in the user/purchaser information.

H. Certification Label

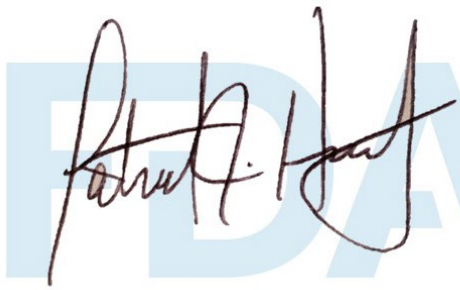
The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 2022-V-0103 effective on January 31, 2022

This variance action will be posted to the Docket associated with your variance request and made available for public view online at www.regulations.gov. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Should you have any questions or comments pertaining to this letter, please contact Lowell Howard by email at Lowell.Howard@fda.hhs.gov or by telephone at (240) 402-0413. For general inquiries, email RadHealth@fda.hhs.gov. In any follow-up correspondence, please clearly reference FDA Variance Number 2022-V-0103 and include a contact email address.

Sincerely,



For:
Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

cc: FDA Dockets Management Staff, Docket Number 2022-V-0103

Enclosure: Attachment A.3.1

ATTACHMENT A.3.1:

1. This variance is not transferable to any other firm or person and applies only to the specific products identified in the variance.

2. Classification of all LIPs shall be in accordance with the guidance document, Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57), or with IEC 62471-5:2015 as described in Laser Notice No. 57.

3. All laser products, systems, shows, and projectors shall be certified to comply with applicable requirements of 21 CFR 1040.10 and the conditions of this variance and be reported as required by 21 CFR 1002.10 and 1002.11 using the reporting guides provided for such purpose. These actions shall be accomplished prior to any introduction into commerce.

4. The annual report required by 21 CFR 1002.13 shall be submitted by September 1st of the current year as a condition for renewal of this variance effective December 31st following the due date of the annual report. The annual report shall also include a list identifying all LIPs used in shows by your firm during the reported year. The list shall include the manufacturer, model designation, and accession number under which each projector was reported. [Note, firms granted a new variance after June 30th do not have an annual report required in the year of issuance, but will have an annual report required in subsequent years.]

5. Effects other than front or rear screen projections shall not be performed. Any additional effects require the submission of a variance amendment request (in accordance with 21 CFR 1010.4) and the filing of product reports or supplements as applicable.

6. LIPs distributed under this variance shall be installed by the firm or by a trained, manufacturer-authorized installer andin accordance with the LIP manufacturer's installation instructions. An authorized LIP installer acting as a dealer or distributor, shall keep sales and installation records in accordance with 21 CFR 1002.40.

   For LIPs not installed by the manufacturer or by a manufacturer-authorized installer, or if installed not in accordance with the manufacturer's installation instructions, the LIP shall not be transferred to any other party, including installers, until the recipient has demonstrated that they have a variance., A notation of the recipient's variance number and its effective date, as applicable, shall be recorded and retained in the records of compliance test results required by 21 CFR 1002.30.

7. The LIP Hazard Zone is the region of space where the projection light from the LIP exceeds the Emission Limits for Risk Group 2 (RG2). Cinema theater installations shall ensure the Hazard Zone is located no less than 2.5 meters above the floor and shall provide no less than 1 meter of horizontal clearance. For installations other than in cinema theaters, the LIP shall be installed at a height

vertically above the floor such that the bottom plane of the Hazard Zone shall be no less than 3 meters above the floor. Horizontal clearance to the hazard zone shall be 2.5 meters, if the vertical clearance distance cannot be met. Alternatively, LIP installations may comply with the horizontal and vertical safety distances in Table 1 of the International Standard ISO 13857:2008(E), if the assumptions in Section 4.1.1 of the standard apply to the environment in which the LIP is being installed. Any human access horizontally to the Hazard Zone, if applicable, shall be restricted by barriers. If human access is possible in an unsupervised environment, the horizontal or vertical clearances shall be increased to prevent exposure to the RG3 hazard zone.

In areas where audience access is restricted, LIP Hazard Zones shall be clearly identified by the posting of warning signs and/or restricted through physical means (such as pressure switches, photocells, barriers, guards, etc.). These requirements apply to temporary areas (such as during setup and alignment procedures) and to final or permanent areas.

8. In addition to requirements found in 21 CFR 1040.10(h), the user information must include:

- Installation instructions that specify the Hazard Zone and clearances required by Condition 7.

- Statement that dealers and distributors of LIPs, including installers, must comply with record keeping requirements described in 21 CFR 1002.40 and discussed in Condition 6.

9. For firm-operated, temporary RG3 LIP installations, including those for customer or trade show demonstrations, the LIP manufacturer shall assure that:

(a) The LIP operatoris located so that all propagating beam paths within the Hazard Zone, and the audience, can be directly observed at all times;

(b) Communication is maintained with other personnel if assisting in surveillance of the LIP projection;

(c) In the event of any unsafe condition, LIP projection light is immediately terminated.

(d) One or more readily accessible controls to immediately terminate LIP projection light is provided.

10. The projection system shall be securely mounted or immobilized to prevent unintended movement or misalignment.

11. The requirements of 21 CFR 1002.30(a)(1) and (2) shall be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show.

These procedures shall be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and any emergency shutdown requirements, and the control of access to radiation areas using the procedures described in the ANSI Z136.1:2007 Standard For The Safe Use of Lasers (available from The Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, Florida 32826) or any other equivalent user consensus standard and, where applicable, State or local requirements.

12. The variance holder shall retain the records of procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance approval letter shall be with the operator or other responsible individual. The variance application, variance approval letter, and if applicable, the most recent annual report, CDRH acknowledgment of receipt for the annual report, current procedures, and records relating to each particular show shall be made available for inspection by FDA and other responsible authorities.

13. For firm-operated, temporary installations, the firm shall maintain complete records of all show itineraries with dates, locations, operator name, and contact information clearly and completely identified. Records shall contain the specific equipment used and a basic description of proposed effects These records shall be available to the Food and Drug Administration upon request.

14. The LIP shall be installed in accordance with any applicable state or local regulations pertaining to operation of laser Class IIIb, Class IV or Risk Group 3 projector systems for public use. It is the joint responsibility of the firm and the installation owner, or manager, to determine whether there are applicable state or local statures and/or regulatory requirements, and if so, to meet those requirements prior to beginning to operate the LIP.