VIA Email

May 14, 2023

Jeff Vyduna
Big Arts Organization, INC.,
1517 North Point Street,
San Francisco, California 94123.

Re: FDA Docket Number: FDA-2022-V-0450
Amendment/Renewal Accession Number: 22A0147-001

Dear Jeff Vyduna :

CDRH is approving, in accordance with 21 CFR 1010.4(c)(1), your petition dated April 17, 2023 to renew your firm's variance approval identified by the FDA Docket Number FDA-2022-V-0450 referenced above.

This variance renewal shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1). The renewed termination date of the variance is December 31, 2023 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.

All other sections from the original variance approval letter remain unchanged, and the conditions of the original variance approval letter continue to apply. The original variance approval letter is attached for reference.

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 The variance will remain in effect until the termination date, unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.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 Neel Samanta by telephone at (240) 402-7532 or by e-mail at Indraneel.samanta@fda.hhs.gov. Email general inquires to RadHealth@fda.hhs.gov. In any follow-up correspondence, please clearly reference the FDA Docket Number and include a contact email address.

Sincerely,

Laurel Burk, Ph.D.
Director
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 5, 2022

Adrienne Plaskett
Big Arts Organization, INC.
1517 North Point Street, #340,
San Francisco, California 94123

Re: FDA Docket Number: FDA-2022-V-0450
Accession Number: 22A0147

Dear Adrienne Plaskett:

The Center for Devices and Radiological Health (CDRH) is approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Big Arts Organization, INC. ("the firm"), dated March 23, 2022, 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

FDA-2022-V-0450

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 Class IIIb (3B) and IV (4) laser light shows assembled and produced by the firm that incorporate any Class IIIb (3B) and/or IV (4) laser projector that has been reported to CDRH and certified by the manufacturer under an appropriate CDRH approved variance, except:

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

2. Projection systems designed or intended to produce audience scanning effects.

The firm's laser light shows may be presented in planetariums or other domed structures, theaters, hotel meeting rooms and ballrooms, store displays, trade shows and conventions, nightclubs, pavilions, indoor and outdoor arenas, museums and outdoor unenclosed areas.

The effects employed may be front and rear screen projections, refractive and diffractive effects, multiple reflections, and the use of fog, smoke or other scattering enhancing material. All laser effects must terminate on a nearby, non-reflective surface, unless a letter of no objection is obtained from FAA (see Attachment B).

E. Provisions From Which Variance is Granted

This variance is granted from 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 (3R).

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 referred to in Item E above, the conditions as specified below in Variance Attachment A and Variance Attachment B shall apply to the products 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 Section 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

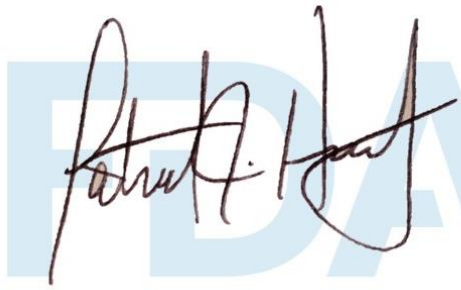
The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number FDA-2022-V-0450 effective on the date of this letter.

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 Zakary Elliott by email at zakary.elliott@fda.hhs.gov or by telephone at (240) 402-9382. In any follow-up correspondence, please clearly reference FDA Variance Number FDA-2022-V-0450 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 FDA-2022-V-0450

Enclosures: Attachments A and B

Variance Attachment A

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

2. 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.

3. 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. [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.]

   The annual report shall include a list identifying all laser light show projectors used in shows by your firm during the reported year. The list shall include manufacturer, model designation, and accession number under which each projector was reported.

4. Effects not specifically indicated in this variance approval shall not be performed. Any additional effects require the submission of an amendment request (using Form 3147 or in accordance with 21 CFR 1010.4) and the filing of product reports or supplements as applicable.

5. Laser projection systems and light shows manufactured, assembled, produced, or distributed under this variance shall not be transferred to any other party until the recipient has demonstrated that they have a variance, as required, in effect that permits them to produce certified laser light shows incorporating these laser projection systems. A notation of the recipient's variance number and its effective date, as applicable, shall be entered and retained in the records of compliance test results required by 21 CFR 1002.30.

6. Scanning, projection, or reflection of laser and collateral radiation (light show radiation) into audience or other accessible, uncontrolled areas shall not be permitted at any point except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.

7. Access to radiation levels in excess of the limits of Class I (1) by any person other than operators, performers, or employees shall not be permitted at any point less than 3.0 meters above any surface upon which such persons are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted.

Operators, performers, and employees shall not be required or allowed to view radiation above the limits of Class I (1) or be exposed to radiation above the limits of Class II (2).

8. All laser light shows shall be under the direct and personal control of a trained, competent operator(s). The operator(s) shall:

    a) Be an employee of the variance holder who shall be responsible for the training and conduct of the operator;

    b) Be located where all propagating beam paths, their terminations, and the audience can be directly observed at all times;

    c) Be in communication with personnel assisting in surveillance of the laser display;

    d) Immediately terminate (or designate the termination) of the emission of light show radiation in the event of any unsafe condition and, for open air shows, at the request of any air traffic control officials; and

    e) Ensure one or more readily accessible controls are provided to immediately terminate laser radiation.

9. The maximum laser projector output power shall not exceed the level required to obtain the intended effects.

10. The projection system (i.e., the projector and all other components used to produce the lighting effects) shall be securely mounted or immobilized to prevent unintended movement or misalignment. In addition:

    a) Electronic controls and circuits shall be adequately shielded to prevent electromagnetic sources (e.g., walkie-talkies, headset radios, wireless microphones, cellular telephones, etc.) in the vicinity of the projector, its active projection heads, and control system(s) from causing the laser emissions to be misdirected from their intended target area.

    b) Beam masking to prevent projections into prohibited areas or directions or overfilling of screens, beam stops, targets, etc. shall be incorporated as an inherent part of the system design. Such devices may be adjustable if the system's intended use environment requires such capability.

11. In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projectors/systems shall provide to parties who purchase, lease, or borrow the equipment, adequate user's instructions for safe installation and operation. These instructions shall also explain the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from the Center for Devices and Radiological Health (CDRH) prior to the introduction into commerce of any laser light shows.

12. 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, emergency shutdown requirements, and the control of access to radiation areas using the procedures described in the ANSI Z136.1:2014 Standard For The Safe Use of Lasers (available from The Laser Institute of America, 1242 Research Parkway, Suite 130, Orlando, Florida 32826, https://www.lia.org/) or any other equivalent user consensus standard and, where applicable, State or local requirements.

    Laser radiation areas which can contain radiation levels above Class I (1) or II (2) as applicable, shall be clearly identified by the posting of warning signs and/or restricting access 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.

    The variance holder shall retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, Laser Notice 55, the most recent annual report, CDRH acknowledgment of receipt for the annual report, current procedures, and records relating to each particular show shall be with the operator or other responsible individual and shall be made available for inspection by FDA and other responsible authorities.

13. The firm or person to whom this variance is issued 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, a basic description of proposed effects and a statement of the maximum power output used. These records shall be available to the FDA upon request.

14. Advance written notification shall be made as early as possible to appropriate Federal, State, and local authorities providing show itinerary with dates and locations clearly and completely identified, and a basic description of proposed effects including a statement of the maximum power output intended. Such notifications shall be made, but not necessarily be limited, to:

    a) The Federal Aviation Administration (FAA) and the Department of Defense (DOD) for any unterminated projections into open airspace at any time (i.e., including setup, alignment, rehearsals, performances, etc.). If the FAA or DOD objects to any laser effects, the objections shall be resolved, and any conditions requested by FAA and DOD will be adhered to. If these conditions cannot be met, the objectionable effects shall be deleted from the show.

    b) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of State and local law shall be satisfied, and any objections raised by local authorities shall be resolved or the effects deleted.

Variance Attachment B

This attachment provides information to assist when notifying the Federal Aviation Administration (FAA) and State radiation control authorities of proposed outdoor laser light shows (demonstrations) as required by Condition #15 in Variance Attachment A.

FAA Notification

The FAA must be notified 30 days prior to any shows or demonstrations in which laser light beams may be directed or reflected into airspace (unterminated effects), including during set-up, alignment, and rehearsals. The FAA recognizes that industry conditions may not always permit the advance notice desired, however, if there isn't sufficient time to conduct an aeronautical study to determine airspace effects is essential to air safety, FAA may not permit the proposed unterminated laser effects. This is particularly true when the nature of the demonstration is in close proximity to an airport or would necessitate protection of large amounts of airspace. In these cases, it may be impossible for the FAA to respond to short-notice requests.

Please refer to FAA Advisory Circular Number 70-1A (AC No: 70-1A) for detailed notification information, the notification form (FAA Form 7140-1), instructions for completing the form, and regional FAA contact information to which notification should be submitted. Notifications should contain sufficient technical information to allow proper evaluation. The primary concern is the range and elevation from the source of the airspace which may be affected by the display. AC No:70-1A can be found on the following website:

https://www.faa.gov/documentLibrary/media/Advisory_Circular/AC_70-1_A_Outdoor_Laser_Operation.pdf

State and Local Radiation Control Authorities

State and local authority requirements should be observed and notification should be made when required. The following website has contact information for radiation protection programs for each state:
https://www.crcpd.org/mpage/Map