DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 19, 2018

Ref. FDA Docket No. 2012-V-0620
Accession No. RH12A0127-003, 004, 005, 006, 007

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In accordance with 21 CFR 1010.4(c)(1) notice is given that the petitions of KVANT LTD.("the firm") dated 3/22/18, for amendment 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

2012-V-0620

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter. This variance shall be considered extended for one year effective December 31st following the due date of an annual report if, and only if, the annual report has been submitted as required by 21 CFR 1002.13.

C. Termination Date

This variance shall be terminated after 12/31/2018, unless extended as provided under B above. In subsequent years, the variance shall be terminated, in accordance with Attachment A, Condition 2.b of this variance, after December 31st following the due date of an annual report if the annual report has not been submitted as required by 21 CFR 1002.13.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb and IV laser light shows assembled and produced by KVANT LTD. incorporating the following certified projectors: the firm's projector models named Maxim, Clubmax, Spectrum, or Atom with suffixed charecter strings indicating maximum projector power, available colors, control interface (FB4, etc),and ending with "-GK" to indicate testing and certification in accordance with United States regulations.

The firm also may manufacture, report, and certify Class IIIb or IV laser light show projectors under this variance. Further, the firm may incorporate into their laser light shows any laser projection systems, which have been certified and reported by the firm or by another 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 or intended to produce audience scanning effects.

The firm's laser light shows may be presented in the firm's laser light shows may be presented at trade show, convention, business demo room.

The effects employed may be front screen projections, reflections from stationary or mirrored surfaces, fog, smoke, or other 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, which requires each demonstration laser product to comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product, and requires that demonstration laser products 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

The conditions specified in Attachments A and 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), the product performs a necessary function or is intended for a special purpose which cannot be accomplished with equipment that meets the requirements of 21 CFR 1040.11(c). 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 2012-V-0620 effective as of the

date of this letter.

This 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 a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,

for

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

CC: FDA Division of Dockets Management, Docket No. 2012-V-0620
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 the variance.

2. (a) 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.

   (b) 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.]

   (c) The annual report shall also 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.

3. 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.

4. 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.

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

6. Access to radiation levels in excess of the limits of Class I 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 to be. Operators, performers, and employees shall not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits of Class II.

7. Any product which relies on scanning to meet access, exposure, or product class limits shall incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.

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; and

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

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

   (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.

    Electronic controls and circuits shall be adequately shielded to prevent electromagnetic sources (e.g., walkie-talkies, head set 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.

    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, 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.

    Laser radiation areas which can contain radiation levels above Class I or II 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, the 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 Food and Drug Administration 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 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 can not 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.

Unless otherwise specified by regulation (e.g., variance applications), all correspondence to be provided to the CDRH shall be addressed to:

Center for Devices and Radiological Health
Magnetic Resonance and Electronic Products Branch
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
WO66-G609
Silver Spring, MD 20993-0002
Phone: Voice: (301) 796-5710
FAX: (301) 847-8502

Regional Radiological Health Representatives and Electro-Optics Specialists as of 4/11/2014

For States: ME, NH, VT, MA, NY, CT, RI

George T. Allen, Jr., (RRHR, NER)
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For States: TN, NC, SC, GA, FL, PR, AL, MS, LA

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Variance Attachment B

This attachment provides the list of information to be provided to the Federal Aviation Administration (FAA) and the Department of Defense (DOD) in notifications of outdoor laser light shows (demonstrations) which cause projections into the sky. This information is required to permit FAA and DOD jointly to do the aeronautical study necessary to determine whether or not the proposed effects are objectionable.

CONTENT OF NOTIFICATIONS

1. Proponent notifications to the FAA regional office will include the following information on all proposed outdoor demonstrations:

   (a) Laser group/company (point of contact)

   (b) Business addresses

   (c) Telephone number

   (d) CDRH Variance number and expiration date

   (e) Date(s) and time(s) of setup and alignment

   (f) Date(s) and time(s) of shows(s), including show length and running time

   (g) Location of the show

      (1) Show place name and address

      (2) Latitude and longitude of show place in Degrees, Minutes, and Seconds

      (3) Maps (USGS 7.5 Quadrangle or acceptable alternate)

   (h) Class/Type of Laser (CW or Pulsed*)

   (i) Maximum emitted power (watts)/repetition frequency (kHz) at the projector as certified to CDRH

   (j) Azimuth direction of beams

   (k) Minimum and maximum elevation of beams in degrees above the horizon

   (l) Beam divergence (milliradians)

   (m) Maximum distance from source for irradiance of 2.6 milliwatts per centimeter squared, 100 microwatts per centimeter squared, and 5 microwatts per

centimeter squared based on maximum emitted power

(n) Maximum altitude above source for irradiance of 2.6 milliwatts per centimeter squared, 100 microwatts per centimeter squared, and 5 microwatts per centimeter squared based on maximum emitted power

(o) A diagram depicting all beam arrays terminated/unterminated

(p) Laser safety officer/operator

(1) Local address and phone number, to include an operational telephone number at the site

(2) Additional safety procedures such as communications procedures during the show other visual aircraft spotting

(q) Quality Assurance Program, describing physical/procedural control of:

(1) Laser power

(2) Beam divergence

(3) Azimuth and elevation of beam paths

(4) Beam termination surfaces

(5) Emergency shutdown procedures

Note: Repetitive pulsed laser data (e.g., equipment type, pulse duration, etc.) shall be validated by the CDRH, and shall accompany submission to the FAA.

2. Supplementary information if applicable. Include the CDRH letter validating the measures which result in a smaller affected area than that shown in the Laser System Power Range Table (Table 29 2-1, FAA Order JO 7400.2L).

SUBMISSION OF PROPOSAL

The last condition of Attachment A of the variance requires that you provide written notification to the Federal Aviation Administration (FAA) and the Department of Defense (DOD) and satisfy any requirements they may specify before conducting an outdoor laser light show. In detail, this requirement means that:

1. All notifications are to be directed to the Air Traffic Division at the FAA regional office having jurisdiction over the area where the laser show will take place.

2. FAA needs at least 30 days advance notice to process a request and conduct an aeronautical study. The FAA recognizes that industry conditions may not always permit the advance notice desired. While FAA endeavors to accommodate all requests, proper conduct of the aeronautical study to determine airspace effects is essential to air safety. 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.

3. Notifications are required for all demonstrations in which laser light beams may be directed or reflected into airspace (including set up, alignment, and rehearsals). 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.

4. A proponent wishing to provide supplementary information about measures which will result in a smaller actual danger area than that shown in the Laser System Power Range Table (Table 29 2-1, FAA Order JO 7400.2L) should submit the data in advance to CDRH for review. CDRH will validate the information and issue a letter to the proponent to include with their notification to the FAA.