DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 21 2005

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Ref: FDA Docket No. 2005V-0154
Accession No. 05A2061

Ms. Mariana Gosheva
Manager
Spectronika Ltd.
No. 34 3020 St. 1360
Sofia, Bulgaria

Dear Ms. Gosheva:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Spectronika Ltd., dated April 19,2005, for 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**

2005V-0154

B. **Effective Date**

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. **Termination Date**

This variance shall be terminated two (2) years from the date of this letter.

D. **Product for Which Variance is Granted**

This variance is granted for the Class IV laser light shows and projectors assembled and produced by Spectronika Ltd. The Spectronika laser light shows and displays will incorporate a certified Spectronica Coppervapor "OGI" projector system containing a CuBr (511nm-578nm) laser which will be separately certified if removable in accordance with 21 CFR 1040.10(c)(2).

The shows will be presented from temporary installations in all types of facilities or outdoor, unenclosed areas for five days or less. The effects employed may be front or rear screen projections, multiple reflection/diffraction effects, reflections from stationary mirrors, 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

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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.

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 ard 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 2005V-0154 effective DEC 21 2005 .

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. 2005V-0154

Attachments A and B

Variance Attachment A
Variance No. 2005V-0154
SPRK (Spectronika Ltd.)

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

   (b) be located where all beam paths can be directly observed at all times; and

   (c) immediately terminate 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.

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 Z136.1-1993 Standard For The Safe Use of Lasers (available from The Laser Institute of America, 1242 Research Parkway, Suite 130, 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, 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. 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 Center for Devices and Radiological Health (CDRH), Office of Communication, Education, and Radiation Programs (address below) and the Electro Optic Specialist responsible for the location of the show (addresses below) providing the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and the Accession Number(s) clearly referenced, each notice shall include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance. To be considered timely, this written notice must be submitted 30 days prior to the opening of the subject show or, when the show becomes known to the manufacturer less than 30 days prior to the show date, the required information must be provided verbally in an immediate phone call to CDRH and also confirmed in the formal written notice that includes the date of the phone notification and the name of the official to whom the information was given.

(b) 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.

(c) 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
Electronic Products Branch (HFZ-342)
Office of Communications, Education, and
Radiation Programs
2098 Gaither Road
Rockville, MD 20850
Phone: Voice: (301) 594-3332
FAX: (301) 594-3306

REGIONAL ELECTRO-OPTICS SPECIALISTS **10/19/2005**

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

Emir Galevi
FDA/WEAC (HFR-NE480)
109 Holton Street
Winchester, MA 01890

781-729-5700 x 724
781-729-3593 (fax)

egalevi@ora.fda.gov

For States: TN, NC, SC, GA, FL, PR, AL, MS, LA

Leo J. Lagrotte, EOS
FDA (HFR-SE2585)
3350 Buschwood Park Drive, Room 170
Tampa, FL 33618

813-228-2671 x35
813-228-2046 (fax)

leo.lagrotte@fda.hhs.gov

For States: NJ, DE, MD, DC, VA, PA, WV, KY, OH, IN, IL, MI, WI, MN, ND, SD

James E. Frye, EOS
FDA (HFR-CE450)
6751 Steger Drive
Cincinnati, OH 45237

513-679-2700 x149
513-679-2772 (fax)

jfrye@ora.fda.gov

For States: IA, MO, AR, NE, KS, OK, TX, WY, CO, NM, UT

SW Region, EOS
FDA (HFR-SW19)
4040 N. Central Expressway, Suite 900
Dallas, TX 75204

214-253-4930
214-253-4960 (fax)

For States: AK, AZ, Southern CA, ID, MT, OR, WA

Frank Eng, EOS
FDA (HFR-PA1530)
96 N. Third Street, Room 325
San Jose, CA 95112

408-291-7548 x15
408-291-7228 (fax)

feng@ora.fda.gov

For States: AK, Northern CA, HI, ID, MT, NV, OR, WA

Gary Zaharek, EOS
FDA (HFR-PA1530)
96 N. Third Street
San Jose, CA 95112

408-291-7548 x12
408-291-7228 (fax)

gzaharek@ora.fda.gov

Variance Attachment B
Variance No. 2005V-0154
SPRK

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

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

1. Laser group/company (point of contact).
2. Business addresses.
3. Telephone number.
4. CDRH Variance number and expiration date.
5. Date(s) and time(s) of setup and alignment.
6. Date(s) and time(s) of shows(s).
   (a) Show length
   (b) Running time.
7. Location of the show.
   (a) Show place name and address.
   (b) Latitude and longitude of show place in Degrees, Minutes and Seconds.
   (c) Maps (USGS 7.5 Quadrangle or acceptable alternate).
8. Class/Type of Laser (CW or Pulsed*)
9. Maximum emitted power (watts)/repetition frequency (kHz) at the projector as certified to CDRH.
10. Azimuth direction of beams.
11. Elevation of beams in degrees above the horizon.
    (a) maximum
    (b) minimum
12. Beam divergence (milliradians).
13. Maximum distance from source for irradiance of 2.6 mW/cm^2, 100 $\mu W/cm^2$, and 5 $\mu W/cm^2$ based on maximum emitted power.
14. Maximum altitude above source for irradiance of 2.6 mW/cm^2, 100 $\mu W/cm^2$, and 5 $\mu W/cm^2$ based on maximum emitted power.
15. A diagram depicting all beam arrays terminated/unterminated.
16. Laser safety officer/operator:
    (a) Local address and phone number, to include an operational telephone number at the site.
    (b) Additional safety procedures:
        (1) Communications procedures during the show.
        (2) Visual aircraft spotters.
        (3) Other.

17. Quality Assurance Program, describing physical/procedural control of:
    (a) laser power
    (b) beam divergence
    (c) azimuth and elevation of beam paths
    (d) beam termination surfaces
    (e) 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.

b. 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 28-2-1, FAA Order 7400.2E, Chg. 2).

SUBMISSION OF PROPOSAL

a. 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.

b. 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 enceavors 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 28-2-1, FAA Order 7400.2E, Chg. 2) 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.