

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY OR DEVICE	Form approved: OMB No. 0910-0025 Expiration Date: October 31, 2000 DOCKET NUMBER
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NOTE. No laser light show or display device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this application in accordance with 21 CFR 1010.4

INSTRUCTIONS

1. Check all applicable boxes and type or print the requested information.
2. Submit an original and four (4) copies.
3. Mail your application to the FDA Dockets Management Branch, Room 1065, 5630 Fishers Lane, Rockville, MD 20852.
4. Enter Docket Number if assigned.

1. NAME OF COMPANY –
SPECTRONIKA LTD.

2. ADDRESS OF COMPANY (Include ZIP Code)
No. 34 3020 St. 1360, Sofia, Bulgaria

3. NAME OF RESPONSIBLE PERSON Mariana Gosheva	4. TELEPHONE NO. (Include area code) 011-359-888-701-982	5. DATE OF SUBMISSION March 15, 2005
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6. The applicant requests the variance to be in effect for a period of 2 years from the date of issue and requests to manufacture 1 units under this variance. (In general the Agency will approve a variance for only two years. If a longer period is requested a justification must be attached as part of the application.)

7. PRODUCT DESCRIPTION AND USE

a. LIST NAME AND MODEL NUMBER(S)
Copper Vapor Laser "Ogi": OM5WCVL, OM6WCVL, OM7WCVL, OM8WCVL

<p>b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED</p> <p><input checked="" type="checkbox"/> A LASER DISPLAY DEVICE <input type="checkbox"/> A PROJECTOR FOR A LASER LIGHT SHOW <input checked="" type="checkbox"/> A LASER LIGHT SHOW <input type="checkbox"/> OTHER (Specify)</p> <p>c. PRODUCT IS INTENDED FOR USE IN A</p> <p><input checked="" type="checkbox"/> PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE <input checked="" type="checkbox"/> THEATER <input checked="" type="checkbox"/> DISCOTHEQUE OR NIGHT CLUB <input checked="" type="checkbox"/> PAVILION <input checked="" type="checkbox"/> INDOOR ARENA <input checked="" type="checkbox"/> OUTDOOR ARENA <input checked="" type="checkbox"/> MUSEUM <input checked="" type="checkbox"/> OUTDOOR ENCLOSE AREA <input type="checkbox"/> OTHER (Specify)</p> <p>d. PRODUCT IS INTENDED TO BE USED</p> <p><input type="checkbox"/> AT ONLY ONE (fixed) LOCATION <input checked="" type="checkbox"/> AT A VARIETY OF (tour) LOCATIONS <input type="checkbox"/> OTHER (Specify)</p>	<p>e. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION</p> <p><input type="checkbox"/> MORE THAN 15 DAYS <input type="checkbox"/> MORE THAN 5 BUT NOT MORE THAN 15 DAYS <input checked="" type="checkbox"/> LESS THAN 5 DAYS</p> <p>f. TOUR IS INTENDED TO RUN FOR</p> <p><input type="checkbox"/> MORE THAN 6 MONTHS <input type="checkbox"/> 1-6 MONTHS <input type="checkbox"/> LESS THAN 1 MONTH <input type="checkbox"/> NOT APPLICABLE (not a tour) <input checked="" type="checkbox"/> OTHER (Specify) Unknown at time of application</p> <p>g. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS</p> <p><input checked="" type="checkbox"/> FRONT SCREEN PROJECTIONS <input checked="" type="checkbox"/> REAR SCREEN PROJECTIONS <input type="checkbox"/> HOLOGRAPHIC DISPLAYS <input checked="" type="checkbox"/> MULTIPLE REFLECTIONS (multiple channel or diffraction effects) <input type="checkbox"/> AUDIENCE SCANNING <input checked="" type="checkbox"/> REFLECTIONS FROM STATIONARY MIRROR(S) OR MIRRORED SURFACES <input type="checkbox"/> STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES <input type="checkbox"/> SCANNING IRRADIATION OF ROTATING MIRROR BALL(S) <input checked="" type="checkbox"/> FIBER OPTIC PROJECTIONS <input checked="" type="checkbox"/> FOG, SMOKE OR OTHER SCATTERING EFFECTS <input type="checkbox"/> OTHER (Specify)</p>
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8. LASER RADIATION LEVELS

LASER MEDIUM (Ar, He-Ne, etc.)	WAVELENGTHS (nm)	PEAK POWER (Watts)
CuBr	511nm-578nm	10 Watts

9. IF ANY LASER RADIATION'S PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE. Average pulsed duration: 30 ns (FW HM)

10. REASON FOR REQUESTING VARIANCE

COMPLIANCE WITH THE LIMITS OR 21 CFR 1040.11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT POWER TO THE EXTENT THAT THE DESIRED EFFECTS WOULD NOT BE SUFFICIENTLY VISIBLE

OTHER OR ADDITIONAL EXPLANATION (Specify).

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11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD

IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS OF CLASS I OR CLASS II

IT IS PROPOSED TO DEVIATE FROM THE PROVISION OF 21 CFR 1040.11(c) AS FOLLOWS:

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS, USE OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11(c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA

OTHER OR ADDITIONAL ADVANTAGES *(describe and explain)*

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. *(Check as many boxes, as apply. Explain any boxes not checked using additional sheets as necessary. If appropriate, state any other means of radiation protection that will be used)*

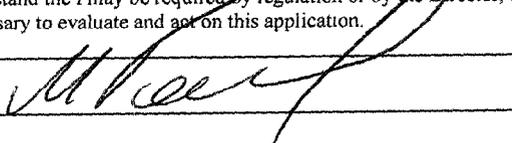
- a. ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL COMPLY WITH 21 CFR 1040.10 FOR LASER PRODUCTS OF THEIR CLASS *(Specify class(es))* IV
- b. LASER AND COLLATERAL RADIATION MEASURED WHERE THE AUDIENCE IS LOCATED, SHALL NOT EXCEED THE LIMITS OF CLASS I DURING OPERATION *(includes reflections from targets and scattering materials).*
- c. OPERATORS, PERFORMERS AND EMPLOYEES WILL BE ABLE TO PERFORM THEIR FUNCTIONS WITHOUT THE NEED TO VIEW LASER AND COLLATERAL RADIATION IN EXCESS OF THE LIMITS OF CLASS I AND WITHOUT BEING EXPOSED TO LASER RADIATION IN EXCESS OF THE LIMITS OF CLASS II HUMAN EXPOSURE TO CLASS III OR CLASS IV LEVELS OR RADIATION SHALL NOT BE PERMITTED.
- d. SCANNING SERVICES, INCLUDING MIRROR BALLS, WILL INCORPORATE A SCANNING SAFEGUARD TO PREVENT LASER EMISSION IF SCAN FAILURE OR OTHER FAILURE CAUSING A CHANGE IN EITHER SCAN VELOCITY OR AMPLITUDE WOULD RESULT IN VIOLATION OF ITEMS 13b OR 13c.
- e. WHEN LASER LIGHT SHOW OR DISPLAYS ARE NOT OPERATED AT ALL TIMES UNDER THE DIRECT CONTROL OF AN OPERATOR, LASER RADIATION LEVELS WILL NOT EXCEED THE LIMITS OF CLASS II AT ANY POINT LESS THAN 6 METERS ABOVE ANY SURFACE UPON WHICH A PERSON IN THE AUDIENCE IS PERMITTED TO STAND, OR AT ANY POINT LESS THAN 2.5 METERS IN LATERAL SEPARATION FROM OR BELOW ANY POSITION WHERE A PERSON IN THE AUDIENCE IS PERMITTED DURING THE PERFORMANCE OR DISPLAY. A DESIGNATED PERSON(S) WILL BE RESPONSIBLE, AT ALL TIMES DURING THE SHOW OR DISPLAY, FOR THE IMMEDIATE TERMINATION OF LASER RADIATION IN THE EVENT OF EQUIPMENT MALFUNCTION, AUDIENCE UNRULINESS, OR OTHER UNSAFE CONDITIONS. ONE OR MORE READILY ACCESSIBLE CONTROLS TO EFFECT IMMEDIATE TERMINATION OF LASER RADIATION WILL BE PROVIDED FOR THIS PURPOSE.
- f. WHEN LASER LIGHT SHOWS OR DISPLAYS ARE OPERATED AT ALL TIMES UNDER THE DIRECT CONTROL OF A TRAINED OPERATOR LASER RADIATION LEVELS WILL NOT EXCEED THE LIMITS OF CLASS II AT ANY POINT LESS THAN 3 METERS ABOVE ANY SURFACE UPON WHICH A PERSON IN THE AUDIENCE IS PERMITTED TO STAND OR 2.5 METERS IN LATERAL SEPARATION FROM OR BELOW ANY POSITION WHERE A PERSON IN THE AUDIENCE IS PERMITTED TO BE UNLESS PHYSICAL BARRIERS RESTRICT ACCESS BY THE AUDIENCE TO SUCH LEVELS. THE OPERATOR WILL MAINTAIN CONSTANT SURVEILLANCE OF THE LASER DISPLAY AND IMMEDIATELY TERMINATE EMISSION OF LASER RADIATION IN THE EVENT OF EQUIPMENT MALFUNCTION, AUDIENCE UNRULINESS OR OTHER UNSAFE CONDITIONS.
- g. THE MAXIMUM LEVELS OF LASER RADIATION *(output power)* WILL NOT EXCEED THOSE REQUIRED TO PERFORM THE INTENDED FUNCTION OF THE PRODUCT.
- h. WRITTEN SET-UP, ALIGNMENT AND TEST PROCEDURES WILL BE PROVIDED TO AND FOLLOWED BY THE OPERATOR OR OTHER RESPONSIBLE PERSON PRIOR TO USE OF A LASER LIGHT SHOW AT EACH LOCATION. THESE STEP-BY-STEP PROCEDURES WILL BE DESIGNED SO THAT WHEN FOLLOWED, THE LASER LIGHT SHOW WILL COMPLY WITH THE CONDITIONS OF THE APPROVED VARIANCE. THE RESULTS OF THE REQUIRED TEST AND CHECKS WILL BE RECORDED AND A COPY RETAINED WITH THE LIGHT SHOW BY THE OPERATOR OR OTHER RESPONSIBLE PERSON. THE RECORD WILL INCLUDE (1) SKETCHES SHOWING THE LOCATION OF THE LASER PROJECTOR(S), OPERATOR(S), PERFORMER(S), AUDIENCE, BEAM PATHS, VIEWING SCREENS, WALLS, MIRROR BALLS, AND OTHER SURFACES THAT MAY BE STRUCK BY THE LASER BEAMS; (2) INFORMATION ON SCANNING PATTERNS, VELOCITY AND FREQUENCY; AND (3) LASER RADIATION LEVELS.
- i. SET-UP, ALIGNMENT, CHECKOUT AND TESTING SHALL BE PERFORMED USING THE MINIMUM LASER RADIATION LEVELS NECESSARY.
- j. PROCEDURES WILL BE ESTABLISHED AND FOLLOWED FOR THE WRITTEN NOTIFICATION OF APPROPRIATE FEDERAL, STATE AND LOCAL AGENCIES OF THE ITINERARIES, OR ANY OTHER REQUIRED INFORMATION, SPECIFICALLY, THE FEDERAL AVIATION ADMINISTRATION (FAA) WILL BE NOTIFIED IN ADVANCE OF SHOWS USING PROJECTIONS INTO THE SKY. STATE AND LOCAL RADIATION CONTROL OFFICES WILL BE NOTIFIED IN ADVANCE OF ALL SHOWS WITHIN THEIR RESPECTIVE JURISDICTIONS *(Lists of Federal and State offices are available from the Bureau of Radiological Health upon request.)*

14 (X) THE BUREAU OF RADIOLOGICAL HEALTH WILL BE NOTIFIED OF THE INTENDED PLACE AND DATE OF ASSEMBLY (tour itinerary) OF EACH LASER LIGHT SHOW TO BE GIVEN UNDER THE APPROVED VARIANCE AS SOON AS THE PLACE AND DATE CAN BE DETERMINED BY THE APPLICANT. IN ADDITION, A DESCRIPTION OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE UTILIZED IN EACH LOCATION, IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE CONDITIONS OF THE VARIANCE, WILL BE PROVIDED TO THE BUREAU OF RADIOLOGICAL HEALTH. THIS NOTIFICATION WILL BE SENT TO THE DIRECTOR, DIVISION OF COMPLIANCE, HFX-400, BUREAU OF RADIOLOGICAL HEALTH, 5600 FISHERS LANE, ROCKVILLE, MARYLAND 20857.

15 REMARKS

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted/will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand the I may be required by regulation or by the Director, Bureau of Radiological Health to supply such other information that may be necessary to evaluate and act on this application.

16 SIGNATURE 

17. TITLE
Manager of Spectronika Ltd.