DEPT. OF HEALTH AND HUMAN SERVICES 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 No. 57R0068 **DOCKET NUMBER**

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 Hearing Clerk, Food and Drug Administration Room 4-65, 5600 Fishers Lane, Rockville, MD 20857
4. Enter Docket Number if assigned

1. NAME OF COMPANY
The Best of Time

2. ADDRESS OF COMPANY (Include ZIP Code)
1354 W. 800 North., Clinton, UT 84015

3. NAME OF RESPONSIBLE PERSON	4. TELEPHONE NO. *(Include area code)*	5. DATE OF SUBMISSION
Justin Chatterton	801-549-8736	December 19, 2003

6. The applicant requests the variance to be in effect for a period of _2_ years from the date of issue *(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)

LUMALASER ColorBurst, ColorBurst Jr, Beamburst Diamond 300, BeamBurst Aqua 250, BeamBurst Amber 50

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
__ A LASER DISPLAY DEVICE
__ A PROJECTOR FOR A LASER LIGHT SHOW
_x_ A LASER LIGHT SHOW
__ OTHER *(Specify)*

c. _x_ PROJECTORS ARE INTENDED FOR SALE, LEASE OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A
_X_ PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE
_x_ THEATER
_X_ DISCOTHEQUE OR NIGHT CLUB
__ PAVILION
_X_ INDOOR ARENA
__ OUTDOOR ARENA
__ MUSEUM
__ OUTDOOR ENCLOSED AREA
X OTHER *(Specify)* *School and Church Auditoriums*

e. PRODUCT IS INTENDED TO BE USED
__ AT ONLY ONE *(fixed)* LOCATION
_x_ AT A VARIETY OF *(tour)* LOCATIONS
__ OTHER *(Specify)*

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION
_x_ MORE THAN 15 DAYS
__ MORE THAN 5 BUT NOT MORE THAN 15 DAYS
__ LESS THAN 5 DAYS

g. TOUR IS INTENDED TO RUN FOR
__ MORE THAN 6 MONTHS
__ 1-6 MONTHS
__ LESS THAN 1 MONTH
__ OTHER *(Specify)*

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
_x_ FRONT SCREEN PROJECTIONS
_x_ REAR SCREEN PROJECTIONS
__ HOLOGRAPHIC DISPLAYS
_X_ MULTIPLE REFLECTIONS *(multiple channels or diffraction effects)*
__ AUDIENCE SCANNING
_x_ REFLECTIONS FROM STATIONARY MIRROR(S) OR MIRRORED SURFACES
__ STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES
__ SCANNING IRRADIATION OF ROTATING MIRROR BALL(S)
__ FIBER OPTIC PROJECTIONS
_x_ FOG, SMOKE OR OTHER SCATTERING EFFECTS
__ OTHER *(Specify)*

8. **LASER RADIATION LEVELS**

LASER MEDIUM *(Ar, He-Ne, etc.)*	WAVELENGTHS (nm)	PEAK POWER *(Watts)*
GaALas Diode/GaN	**630-660/410**	**400 mW**
Argon Ion	**454-514**	**400 mW**
DPSS Nd:YV04	**532**	**400 mW**

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE
DC-4 KHZ, 0-80° optical X-Y scan

10. REASON FOR REQUESTING VARIANCE
_x_ COMPLIANCE WITH THE LIMITS OF 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

X 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

X 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. In item 14 "Remarks", justify any boxes not checked, using additional sheets as necessary State any other means of radiation protection that will be used.)

a. X ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 24 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDES PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.

b. X EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED. NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.

c. X SCANNING, PROJECTION, OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ACCESSIBLE UNCONTROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.

d X LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS I WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE. OPERATORS, PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS I OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11 (c).

e. X ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.

f X ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AN PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL

(1) IMMEDIATELY TERMINATE THE EMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION,

(2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND

(3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF OPERATOR

g. X THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.

h. X THE PROJECTION SYSTEM (I E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT. BEAM LIMITS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, ETC.

i. X LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.

j. X IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10 (h), THE MANUFACTURER OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH 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 CDRH PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOWS

k. X THE REQUIREMENTS OF 21 CFR 1002.30 (a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP ALIGNMENT, TESTING, AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10 THE CONDITIONS OF THIS VARIANCE, AND CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI Z136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS LASER RADIATION AREAS WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTED 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 WILL 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 WILL BE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES

I. X ADVANCE WRITTEN NOTIFICATION WILL 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 WILL BE MADE, BUT NOT NECESSARILY LIMITED TO:

(1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ-312),2098 GAITHER ROAD,ROCKVILLE, MD 20880.PROVIDING THE INITIAL AND CLOSING DATES FOR THE FIXED INSTALLATION AND THE ITINERARY FOR MOBILE SHOWS IN ADDITION, UNLESS ALL ASPECTS OF EACH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED. EACH NOTICE WILL 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.

(2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E., INCLUDING SET-UP, ALIGNMENT, REHEARSALS, PERFORMANCES, ETC.) IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND NY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO. IF THESE CONDITIONS CAN NOT BE MET, THE OBJECTIONABLE EFFECTS WILL BE DELETED FROM THE SHOW.

(3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS. ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

14. 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 1002.12 on the laser equipment and show(s). I further understand that 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.

15. SIGNATURE	16. NAME (Type or Print)	17. TITLE
	Justin Chatterton	Owner