DEPARTMENT 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 (Optional) Expiration Date: August 31, 1988 DOCKET NUMBER

NOTE: No laser light show, projection system, or 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 Docket Management Branch (HFA-305), Food and Drug Administration, Room 1-62, 5600 Fishers Lane, Rockville, MD 20857.
4. Enter Docket Number if assigned.

1. NAME OF COMPANY: Pangolin Laser Systems, Inc.

2. ADDRESS OF COMPANY (Include ZIP CODE): 771 South Kirkman Road, #113, Orlando FL 32811

3. NAME AND TITLE OF RESPONSIBLE PERSON: William R. Benner, JR. VP. Engineering

4. TELEPHONE NO. (Include area code): (407) 299-2088

5. DATE OF SUBMISSION: January 1, 1999

6. The applicant requests the variance to be in effect for a period of ____ years from the date of issue.
(In general, the Agency will approve a variance for such one year. 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/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S):
Shows: Pangolin Show A; Pangolin Show B; Pangolin Show C; Projector: Signature 300

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
- [ ] A LASER DISPLAY DEVICE
- [x] A PROJECTOR FOR A LASER LIGHT SHOW
- [x] A LASER LIGHT SHOW
- [ ] OTHER (Specify) _____

c. [ ] 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] HOTEL/MOTEL BALLROOM OR MEETING ROOM
- [x] STORE DISPLAYS
- [x] TRADE SHOW OR CONVENTION
- [x] DISCOTHEQUE OR NIGHT CLUB
- [x] PAVILION
- [x] INDOOR ARENA
- [x] OUTDOOR ARENA
- [x] MUSEUM
- [x] OUTDOOR UNENCLOSED AREA
- [x] OTHER (Specify) _____

e. PRODUCT IS INTENDED TO BE USED
- [x] AT ONLY ONE (fixed) LOCATION
- [x] AT A VARIETY OF (mobile) LOCATIONS
- [ ] OTHER (Specify) _____

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION
- [x] MORE THAN 15 DAYS See 14, remarks
- [x] MORE THAN 5 BUT NOT MORE THAN 15 DAYS
- [x] LESS THAN 5 DAYS

g. TOUR IS INTENDED TO RUN FOR
- [ ] MORE THAN 6 MONTHS
- [ ] 1-6 MONTHS
- [ ] LESS THAN 1 MONTH
- [x] NOT APPLICABLE (not a tour)
- [x] OTHER (Specify) See 14, remarks

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
- [x] FRONT SCREEN PROJECTIONS
- [x] REAR SCREEN PROJECTIONS
- [ ] HOLOGRAPHIC DISPLAYS
- [x] MULTIPLE REFLECTION/DIFFRACTION EFFECTS
- [ ] AUDIENCE SCANNING (Laser light scanning per mechanically intermediate screen)
- [x] REFLECTIONS FROM STATIONARY MIRRORS OR MIRRORED SURFACES (Mirror Balls)
- [ ] STATIONARY IRRADIATION OF ROTATING MIRROR BALLS, ETC.
- [ ] SCANNING IRRADIATION OF ROTATING MIRROR BALLS, ETC.
- [ ] FIBER OPTIC PROJECTIONS
- [x] FOG, SMOKE, OR OTHER SCATTERING ENHANCEMENT EFFECTS
- [ ] OTHER (Specify) _____

8. **LASER RADIATION LEVELS**

LASER MEDIUM (Ar, He-Ne, etc.)	WAVE LENGTHS (nm)	PEAK POWER (Watts)
Argon-Krypton	457-647nM	0.3 (300 milliwatts)

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE
Light intensity controlled by PCAOM, capable of analog modulation up to 300 KHZ.
X-Y Galvanometer scanners can deflect beam up to 80 degrees, at scan rates up to 3KHz

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 SPECIFIED IN 21 CFR 1040.11(c)
- [ ] 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, SHOWS, 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 21 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 STAND 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. [ ] 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 AND PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL

(1) IMMEDIATELY TERMINATE THE EMMISSION 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 THE 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 LIMITERS 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(n), 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 THE 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, 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 RESTRICTING ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELLS, BARRIERS, GUARDS, ETC.). THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS DURING SET-UP 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

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1 ☑ 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 BE LIMITED, TO

(1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ 312), 8757 GEORGIA AVE., SILVER SPRING, MD 20910, 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 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 ANY 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 SHOWS 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

At this time, no contracts have been secured for Laser display.

It is our intention to produce displays at trade shows and similar venues for demonstration purposes. These displays will run the range of only once for a few minutes at a single location, to longer shows repeating at one location for longer periods of time, as yet undetermined.

Pangolin Laser Systems will notify the CDRH with initial show reporting forms for review and acceptance as contracts and demonstration opportunities arise, prior to show setup and performance.

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 and will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE	16. NAME (Type or Print)	17. TITLE
William R. Benner	William R. Benner, JR.	Vice President of Engineering

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