

LASER PRODUCT / LASER LIGHT SHOW ANNUAL REPORT:

Part 1. Identification of Manufacturer

Company name: FSS CORPORATION

Address: ***** , JAPAN

Corresponding Official signature:

Name & title: Shuji Fujinoki

Telephone: (+81-45-812-6269)

Firm name & address, if different from above:

This annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 20** through June 30, 20**.

Part 2. Production Status

- (x) Product were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.
- () No products were manufactured during this period but the firm is still business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.
- () No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.
- () Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

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Part 3. Current Production Tabulation

3.1. All Laser Products

Accession Number	Family Designation	Selling Model Numbers	Product Function	Class	Production Status		
					Active	Discont. (mo/yr)	Plant
0510525-00	N/A	MODEL-***** MODEL-***** MODEL-*****	Measuring	Class 3B	Yes		FSS CORPORATION

Note; Regarding the above additional sensor and other modifications, all concerned laser product report with attachments was revised. Please see the renewal laser product report.

3.2. Laser Light shows

Accession Number	Projector or Show Family Designation	Permanent or Touring	Class	Lasing Media	Production Status	
					No. Shows Performed	Discont. (mo/yr)

Part 4. Procedures for Quality Control and Testing

The written procedures for assessing and controlling radiation safety have been reviewed. (These include phototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate.
 (x) YES () NO

The reports provided to CDRH for each model family currently in production have been reviewed and the procedure contained in them are up-to-date, complete, and accurate.
 () YES (x) NO

If you answered “no” to either question, provide the current procedures in a supplement to the appropriate model family report.

MODEL-***** is the additional model that both focusing distance ***** type and LD type DL-***** are added on March 2014. (another specifications are the same)

- Manufacturer: ***** CO.,LTD
- Part number: DL-***** (Invisible Laser Diode)
- Power: **mW
- Wavelength: ***m

Please see the revised laser product report as attached.

Part 5. Summary of Test Results

Model Number or Name of Show	Number Produced	Number Tested		
		Performance Requirements	Labels	Light show Variance Conditions

Remarks; No shipping products to the USA since product release.

Rev.

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from user, dealer, or others about possible radiation exposure or safety-related failures during use of the product was nothing.

Attach a copy of each letter.

The number of letters received from dealers, distributors, or other concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product was nothing.

Attach a summary of correspondence or a sample. Identify any trends in failed components or adjustments needed during servicing.

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was nothing.

Attach a summary of correspondence or a sample.

Part 7. Distribution Reports

Production facility shipping records and dealer records (when returned) are maintained at FSS CORP. in Japan.

Products can be traced from these records by:

- () Model
- (X) Serial Number
- () Date of Manufacture
- () Other, specify :