U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

This message is to acknowledge receipt of your **Annual Report** , which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (Title 21, Code of Federal Regulations, Subchapter J) as they pertain to the submission information description below. If your submission is a report, it has been filed according to reporting requirements in Title 21, Code of Federal Regulations (CFR), Part 1002. Your submission has been assigned an informal subject title below after "Purpose:". Your submission has been assigned an ACCESSION NUMBER which can be used by you and FDA to identify your submission.

WARNING:
THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY, CONVEY OR CONSTITUTE FDA APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT FDA HAS RECEIVED YOUR SUBMISSION. IT MAY BE REVOKED BY FDA. ITS DISCLOSURE IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

Be advised that failure to comply with FDA regulations may result in notification of affected persons and corrective actions at no cost to the purchaser, pursuant to 21 CFR Part 1003 -- Discovery of Defect or Failure to Comply and 21 CFR Part 1004 -- Repurchase, Repairs, or Replacement of Electronic Products.

Please be aware that the following CDRH Product Code(s) have been assigned to the product(s) described in this report:

RIG defined as Laser Illuminated Projector

If these products will be shipped to the United States, the shipping broker will need to provide the full FDA Product Code at the time of entry, structured as follows:

95R- -IG

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This automated notification from the CeSub Submission Process contains general information about the aforementioned submission:

Accession Number: **2030842-000**

Date Loaded: **Aug 7, 2020**

Document Date: **Aug 7, 2020**

Establishment Name: **SHENZHEN LEPSON TECHNOLOGY CO., LTD.**

Purpose: **This submission is a(n) Annual Report. These Laser Light Show/Display Products cover the period from July 01, 2019 to June 30, 2020.**

Submitter: **Ethan Chen**

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If your current laser light show variance provides for automatic extension of the variance, this annual report will extend your variance to December 31, 2021 if all required annual reports have been submitted on time within the year due since your variance was originally issued, as required by 21 CFR 1002.13. If any of the required annual reports were received after December 31st of the year in which they were due, this acknowledgement letter DOES NOT represent an extension of your variance; your variance has expired, and you must request renewal. Submission of missing or future annual reports will not renew your variance

If you meet all other applicable FDA requirements, you may market the product(s) reported. Please be aware that additional electronic product radiation control or medical device regulations may apply to your product, such as:

> 21 CFR 1002.11, requiring report supplements under certain circumstances following the same reporting forms as used for product reports on your products
>
> 21 CFR 1002.13, requiring annual reports to be submitted each year by September 1 using the appropriate reporting form for annual reports
>
> 21 CFR 1010 – 1050, requiring certification to FDA radiation safety performance standards
>
> 21 CFR 807, requiring manufacturer registration and device listing, and
>
> 21 CFR 807, 812 and 814, requiring medical device clearance or approval

For further information see:

Radiological Health web site – http://www.fda.gov/Radiation-EmittingProducts/default.htm
FDA Electronic Submissions Gateway website –
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

If you have any questions, please contact the Director of the Division of Radiological Health, or the branch chief of your respective product area, as listed on the CDRH Management Directory, under the Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health.
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm

Please include a primary (and optional secondary) contact email address in all submissions (and/or cover letters) to facilitate electronic correspondence.

Sincerely yours,

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health