- - - - - - - - - - DOCUMENT RECEIVED, FILED, & ACKNOWLEDGED - - - - - - - - - -

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

Accession Number: **1710678-000**
Date Loaded: **Jul 20, 2017**
Document Date: **Jul 19, 2017**
Establishment Name: **NIE TECHNOLOGY CO., LTD**
Purpose: **This submission is a(n) Initial Product Report. These Laser Light Show/Display Products include designated model family Laser Projector RGB with model(s) NL69.**

Submitter: **Wallace Xu**
Email: **wallace.xu@zuoce.org**
Reporting Official: **Jianghai Nie**
Email: **yee_willisic@nie-tech.com**
- -

Please note that your firm is required to submit an Annual Report to CDRH every year by September 1.

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

Sincerely Yours,

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