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

FDA LETTER

This message is to acknowledge receipt of your **Initial Product 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.

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

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

Accession Number: 1820814-000

Date Loaded: Sep 12, 2018

Document Date: Sep 12, 2018

Establishment Name: SHANGHAI YUCHANG INDUSTRIAL CO., LTD

Purpose: This submission is a(n) Initial Product Report. These Material Processing Laser Products include designated model(s) LF20, LF30, LF30F, LF20F.

Sincerely yours,

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