Erica Fernandes

From: FDA Radiological Health Electronic Submission Program <cdrhesub@cdrh.fda.gov>
Sent: 07 November 2018 20:17
To: Molly.Chen@newbtl.com; Erica Fernandes
Subject: Acknowledgement of Other Laser Products Product Report, 1821008-000

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 **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.

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

RDW defined as General Purpose Laser Products

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- -DW

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

Accession Number: **1821008-000**
Date Loaded: **Nov 7, 2018**
Document Date: **Nov 2, 2018**
Establishment Name: **BANDWEAVER TECHNOLOGY LIMITED**
Purpose: **This submission is a(n) Product Report. These Other Laser Products include designated model(s) DTS-FL-03-02-4CH, DTS-FL-03-02-2CH, DTS-FL-03-05-2CH, DTS-FL-03-02-1CH, DTS-FL-03-05-4CH, DTS-FL-03-05-1CH.**

Submitter: **Molly Chen**
Email: **Molly.Chen@newbtl.com**
Reporting Official: **Erica Fernandes**
Email: **Erica.fernandes@Bandweaver.com**

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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

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