

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993

August 5, 2016

Reference: 1620534-000

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This is to acknowledge receipt of your July 26, 2016, document, 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 Product Report requirements.

Your document has been assigned an accession number of 1620534-000, and has been classified as a(n) Product Report (pursuant to Part 1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Product Report. These Data Measurement, Transmit, Control Laser Products include designated model family Laser Positioning Device with model(s) Model V1.53L0."

This acknowledgement does not constitute approval of the document. You will be contacted if any questions or comments arise concerning your document.

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, Repair, or Replacement of Electronic Products.

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

All Radiological Reports may be prepared using FDA's Electronic Submissions software which can be downloaded at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>. For more information on the FDA's eSubmitter program please see the following websites:

Radiological Health - <http://www.fda.gov/Radiation-EmittingProducts/default.htm>

Electronic Submissions (instead of paper reports) -  
<http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>

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FDA Electronic Submissions Gateway -  
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

Thank you for your cooperation. If any questions or concerns arise during our review of your report, we will notify you. If you have any questions, contact us at (301) 796-5710.

Sincerely Yours,

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics and Radiological Health  
Center for Devices and Radiological Health

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