



U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Reference: 1911228-001

This is to acknowledge receipt of your November 12, 2019, 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 Initial Product Report requirements.

Your document has been assigned an Accession Number of 1911228-001, and has been classified as a(n) Initial 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) Initial Product Report supplement. These Data Measurement, Transmit, Control Laser Products: Submitting updated information to the LD30xxBI10xxxxIO-yyyy. (Mfg by Carlo Gavazzi Industri A/S). (Formerly known as Carlo Gavazzi Handel A/S)."

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, 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:

REQ defined as Laser Time-Of-Flight Speed Measurement 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- -EQ

Please note that your firm is required to submit an Annual Report to CDRH 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>

FDA Electronic Submissions Gateway -
<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