DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
10903 New Hampshire Avenue
WO66-4617
Silver Spring, MD 20993

August 28, 2014

Reference: 0820025-006

Glenn A Weisel
Compliance Engineer / Laser Safety Officer
Datalogic Automation Inc.
511 School House Road
Telford, PA 18969

This is to acknowledge receipt of your July 14, 2014, 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 0820025-006, 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 supplement. These Utility/Peripheral Laser Products include designated model(s) DS2100N-1300, DS2100N-1400, DS2100N-1310, DS2100N-1410, DS2100N-1304, DS2100N-1404, DS2100N-1314 and DS2100N-1414.".

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 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

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

Accession Number: 0820025-006

Models:
DS2100N-1200; DS2100N-1210; DS2100N-1204; DS2100N-1214
DS2100N-2200; DS2100N-2210; DS2100N-2204; DS2100N-2214

DS2100N-1300; DS2100N-1310; DS2100N-1304; DS2100N-1314
DS2100N-1400; DS2100N-1410; DS2100N-1404; DS2100N-1414

cc: Paolo Morselli
DATALOGIC AUTOMATION S.R.L.
VIA LAVINO 265
MONTE SAN PIETRO
BOLOGNA, ITALY 40050

DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
1350 PICCARD DRIVE
ROCKVILLE, MD 20850

January 10, 2008

Reference: 0820025-000

Shirley Hanna
Technical Service Administrator
Datalogic Automation Inc
3000 Earhart Court , Suite 135
Hebron, KY 41048

This is to acknowledge receipt of your January 7, 2008, 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 Model Change Product Report.

Your document has been assigned an accession number of 0820025-000, and has been classified as a(n) Model Change Product Report (pursuant to Part1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Model Change Product Report. These Utility/Peripheral Laser Products include designated model family(s) Laser Scanner For Bar-Code Reading with Built-in Decoder with model(s) DS2100N-1200, DS2100N-1204, DS2100N-1210, DS2100N-1214, DS2100N-2200, DS2100N-2204, DS2100N-2210 and DS2100N-2214. (Mfg. by Datalogic S.p.A., Italy).".

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

Thank you for your cooperation. If you have questions or comments, please write to the address above or call (240) 276-3332.

Sincerely Yours,

CDR Sean M Boyd
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

cc: Lorenzo Girotti
DATALOGIC AUTOMATION S.R.L.
VIA S. VITALINO 13
LIPPO DI CALDERARA DI RENO
BO, ITALY 40012