

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH  
2098 GAITHER ROAD  
ROCKVILLE, MD 20850, USA

SEPTEMBER 19, 2000

REFERENCE:  
8110701-15

VINCENZO VELARDI  
PRESIDENT  
RALCO S.R.L.  
VIA SCHIAPPARELLI  
27/33-20035 LISSONE  
(MI) ITALIA

THIS IS TO ACKNOWLEDGE RECEIPT OF YOUR SEPTEMBER 12, 2000, 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 medical diagnostic x-ray equipment.

YOUR DOCUMENT HAS BEEN CLASSIFIED AS SUPPLEMENT 15 TO ACCESSION NUMBER 8110701, WHICH IS a product report (initial), (pursuant to Section 1002.10 of the Regulations referenced above).

FURTHER, THE SUBMITTAL HAS BEEN ASSIGNED AN INFORMAL SUBJECT TITLE OF "ADDING COLLIMATOR R 302/A."

THIS ACKNOWLEDGEMENT DOES NOT CONSTITUTE APPROVAL OF THE DOCUMENT. IT WILL BE EVALUATED, AND YOU WILL BE CONTACTED IF ANY QUESTIONS OR COMMENTS ARISE IN THE COURSE OF THAT EVALUATION.

THANK YOU FOR YOUR COOPERATION. IF YOU HAVE QUESTIONS OR COMMENTS, Please write to the address above or call (301) 594-4591.

*for Henry H. Kump*  
THOMAS M. JAKUB, CHIEF  
DIAGNOSTIC DEVICES BRANCH  
DIVISION OF ENFORCEMENT I  
OFFICE OF COMPLIANCE

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH  
2098 GAITHER ROAD  
ROCKVILLE, MD 20850, USA

MARCH 31, 2004

REFERENCE:  
0410458-00

VINCENZO VELARDI  
PRESIDENT  
RALCO S.R.L.  
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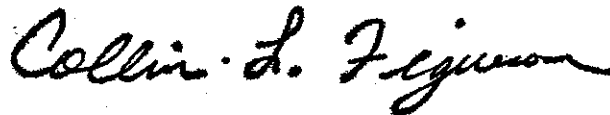
This is to acknowledge receipt of your MARCH 15, 2004, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (Title 21, Code of Federal Regulations, Subchapter J) AS they pertain to laser products (except medical devices):

YOUR DOCUMENT HAS BEEN ASSIGNED AN ACCESSION NUMBER OF 0410458, AND HAS BEEN CLASSIFIED AS a product report (initial), (pursuant to Section 1002.10 of the Regulations referenced above).

Further, the submittal has been assigned an informal subject title of "PRODUCT REPORT (INITIAL) ON LASER PRODUCTS (NON-MEDICAL): FOR THE BEAM LIMITING DEVICE, MODEL R 302L/A X-RAY COLLIMATOR WITH LIGHT."

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 (301) 594-4654.



COLLIN FIGUEROA, CHIEF  
ELECTRONIC PRODUCTS BRANCH  
DIVISION OF ENFORCEMENT B  
OFFICE OF COMPLIANCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH  
10903 New Hampshire Avenue  
WD66-4617  
Silver Spring, MD 20993

July 9, 2010

Reference: 0931110-002

Daniel Kamm

Kamm & Associates  
8870 Ravello Ct  
Naples, FL 34114

This is to acknowledge receipt of your July 1, 2010, 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 Annual Report requirements.

Your document has been assigned an accession number of 0931110-002, and has been classified as a(n) Annual 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) Annual Report supplement. These Medical Diagnostic X-Ray Equipment cover the period from July 01, 2007 to June 30, 2008. (Changing the field illumination lamp from incandescent to LED for All Ralco collimators with field illumination). See report for associated Accession numbers."

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

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,

Sean M. Boyd  
Diagnostic Devices Branch  
Division of Mammography Quality and Radiation Programs  
Office of Communication, Education, and Radiation Programs  
<http://www.fda.gov/Radiation-EmittingProducts/default.htm>