

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

MARCH 8, 2001

REFERENCE:
8311531-07

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

THIS IS TO ACKNOWLEDGE RECEIPT OF YOUR DOCUMENT DATED MARCH 1, 2001, 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 07 TO ACCESSION NUMBER 8311531, 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 THE COLLIMATOR R 302 MLP/A. (TO BE SOLD IN THE USA)."

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. Kemp
THOMAS M. JAKUB, CHIEF
DIAGNOSTIC DEVICES BRANCH
DIVISION OF ENFORCEMENT I
OFFICE OF COMPLIANCE



MAY 11 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Vincenzo Velardi
Ralco S.R.L.
Via. Volturmo 29
20035 Lissone, MI
ITALYRe: K946320/S1
R 302
Dated: April 5, 1995
Received: April 10, 1995
Regulatory Class: II
21 CFR 892.1610/Procode: 90 KPW

Dear Mr. Velardi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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>