

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

October 21, 2008

Reference: 0310253-002

Daniel Kamm
Regulatory Engineer
Kamm & Associates
PO Box 7007
Deerfield, IL 60015

This is to acknowledge receipt of your October 14, 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 Initial Product Report requirements.

Your document has been assigned an accession number of 0310253-002, 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 Medical Diagnostic X-Ray Equipment: Submitting updated information to the Manual X-ray Collimator, model R72. (For Ralco S.R.L).".

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

Please note that your firm is required to submit an Annual Report to CDRH every year on September 1. This report may be prepared using CDRH's electronic submissions software, which can be downloaded at www.fda.gov/cdrh/cesub. You may also submit a paper Annual report, available online at www.fda.gov/cdrh/radhealth.

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

Sincerely Yours,

Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

cc: Vincenzo Velardi
RALCO S.R.L.
VIA DEI TIGLI 13G
20046 BIASSONO
MI, ITALY



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

RALCO S.R.L.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K030487
Trade/Device Name: Model R72 X-Ray Collimator
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray
beam-limiting device
Regulatory Class: II
Product Code: 90 KPW
Dated: June 10, 2003
Received: June 13, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

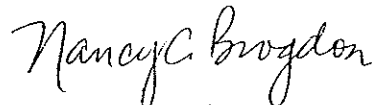
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K030487

Device Name: Model R72 X-Ray Collimator

Indications for Use: Model R72 is intended to be used as an X-Ray beam limitation device on portable and mobile diagnostic X-Ray units.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over the Counter Use _____
(Per 21 CFR 801.109)

David A. Egan
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030487

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>