

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

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

July 6, 2009

Reference: 0910293-000

Daniel Kamm

Kamm & Associates  
333 Milford Road  
Deerfield, IL 60015

This is to acknowledge receipt of your June 30, 2009, 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.

Your document has been assigned an accession number of 0910293-000, and has been classified as a(n) Initial 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) Initial Product Report. These Medical Diagnostic X-Ray Equipment include designated model family Beam-limiting device with model(s) R225 ACS DHHS."

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  
Diagnostic Devices Branch  
Division of Mammography Quality and Radiation Programs  
Office of Communication, Education, and Radiation Programs

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



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 14 2009

RALCO, srl  
% Mr. Daniel Kamm  
Principal Consultant  
Kamm & Associates  
333 Milford Rd.  
DEERFIELD IL 60015

Re: K091517

Trade/Device Name: Model R225 ACS Automatic Collimator  
Regulation Number: 21 CFR 892.1610  
Regulation Name: Diagnostic x-ray beam-limiting device  
Regulatory Class: II  
Product Code: IZW  
Dated: May 20, 2009  
Received: June 02, 2009

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); medical device reporting (reporting of medical

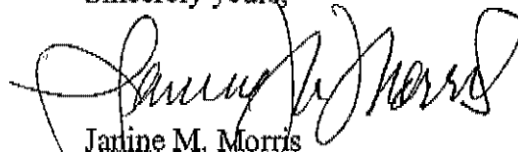
Page 2

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K091517

Device Name: Model R225 ACS Automatic Collimator

**Indications For Use:**

Model R225 ACS Automatic X-RAY Collimator is intended for use in diagnostic radiographic/fluoroscopic applications.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use        
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number  K091517

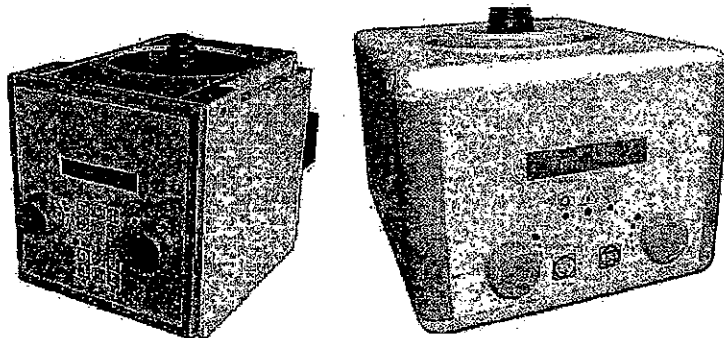
**RALCO srl**  
**Via dei Tigli 13/G**  
**20046 Biassono (mi) Italy**  
**Tel. +39.039.249.7925**  
**Fax: +39.039.249.7799**  
**email: ralco@ralco.it**

**Date prepared: May 18, 2009**  
**Contact person: Vincenzo Velardi, President and CEO**

1. **Identification of the Device:**  
Proprietary-Trade Name: Model R225 ACS Automatic X-RAY Collimator  
Classification Name: collimator, automatic, radiographic, Product Code IZW  
Common/Usual Name: Automatic X-Ray Collimator.
2. **Equivalent legally marketed devices:** K072780, Ralco Model R302DACS Automatic Collimator.
3. **Indications for Use (intended use):** Intended for use in diagnostic/fluoroscopic applications.
4. **Description of the Device:** This x-ray collimator Multilayer, square-field, automatic collimation system. Stepper motors control the movements of shutters and the additional filter. There is a mounting plane at 80 mm (3.15") from the focus. A microprocessor circuit controls the stepper motors and provides the stepless adjustment of the square field dimensions at variable FFD (SID). The field dimensions may be decreased and increased to the set value by two knobs placed on the collimator front panel.
5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, safety test, and laboratory testing indicates that the new device is as safe and effective as the predicate device. The predicate employs a round field, same as our new device. The new device conforms to US Performance Standards and is CSA Listed to US Standards for safety for medical devices.
6. **Conclusion:** After analyzing both bench and safety testing data, it is the conclusion of Ralco that the Model R225 ACS is as safe and effective as the predicate device, has few technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate device.

**Predicate**

**R225 ACS**



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>