510(K) Summary, K09/517

JUL 14 2009

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.

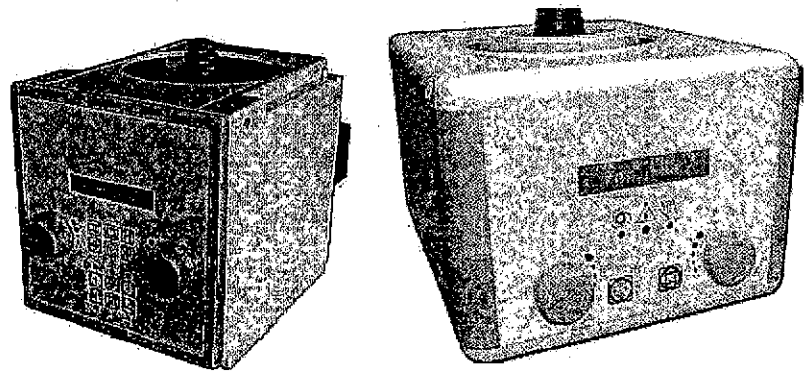
3. **Indications for Use** (intended use): Intended for use in diagnostic/fluoroscopic applications.

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
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

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