K030487

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EXHIBIT 2

510(k) Summary of Safety and Effectiveness

RALCO srl
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June 10, 2003

Contact: Vincenzo Velardi, President and CEO

1. Identification of the Device:
   Proprietary-Trade Name: Model R72 Manually Operated X-Ray Collimator
   Classification Name: COLLIMATOR, MANUAL, RADIOGRAPHIC, Product Code IZX
   Common/Usual Name: Manually Operated X-Ray Collimator.

2. Equivalent legally marketed devices: Ralco Model R302, K946320

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

4. Description of the Device: R72 – X-Ray Collimator:
   External cover in abs plastic
   Single-layer, square field radiological collimator.
   Focus/mounting flange plane distance is 70mm.
   The X-ray field size is limited by two pairs of lead shutters controlled by two knobs located on the sides of the collimator; a lead cone situated near the x-ray anode reduces the off-focus radiation. Its light weight and compact size allow easy positioning and make it ideal for portable units. A table on the front panel allows the operator to read field dimensions set with the knobs.
   Specifications
   Warning: This collimator is not to be used with rotating anode X-ray tubes.
   · External adjustment of mirror angulation.
   · High luminosity provided by a quartz iodide lamp (100W - 24V).
   · Timer limiting projection lamp exposure time to 30 seconds, adjustable, thus extending lamp life and preventing overheating.
   · Radiation protection up to 125 kVp - 4mA .
   · Minimum Inherent filtration 2mm aluminum equivalent. (1mm on request)
   · Continuous film coverage from 0x0 cm to 35x35 cm ±1% FFD at an FFD of 70cm.

5. Safety and Effectiveness, comparison to predicate device. The results of bench and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart, Model R72

Characteristic	Ralco Model R302, K946320	Ralco Model R72 K030487
Intended Use:	As a collimator on Model for operation on stationary units with fixed or rotating anode x-ray tube. Maximum radiation protection 150 kVp. Manual shutter control. Electronic timer for the activation of the light field. Plastic ABS covers	As a collimator on Model for installation on portable and mobile units with fixed anode x-ray tubes. Maximum radiation protection 125 kVp. Two knobs on either side of the unit provide for the manual control of shutters. Electronic timer for the activation of the light-field simulating the x-ray field.
Physical characteristics:		
Size	207mm H x 196mm W x 237mm D.	123 mm H x 168 mm W x 200 mm D
Weight	9.5 kg	3.6 kg
Energy Source:	24 V 100w (lamp)	SAME
Timer	30 sec for light field projection lamp	SAME
KvP	150 KvP max	125 max
Standards and Safety characteristics:		
Performance Standard	21 CFR 1020.30	SAME
Electrical safety:	UL 2601, IEC 60601-1	SAME

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Ralco that the Model R72 is as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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: Diagnoatic 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

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)

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