

510(k) Summary: K072780.

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August 14, 2007

NOV 26 2007

Contact person: Vincenzo Velardi, President and CEO

1. **Identification of the Device:**
Proprietary-Trade Name: Model R302DACS/A Automatic X-RAY Collimator
Classification Name: collimator, automatic, radiographic, Product Code IZW
Common/Usual Name: Automatic X-Ray Collimator.
2. **Equivalent legally marketed devices:** Ralco Collimator, Automatic Radiographic, Tecnomed, Inc, K820306 and K827124 (Manufactured by Ralco but sold in the US by Tecnomed); Advantech Model R600/800 series collimators manufactured by Ralco SRL under K904182; Omega Medical Imaging Model R605FACS, K050092.
3. **Indications for Use (intended use):** Model R302DACS/A Automatic X-RAY Collimator is intended for use in diagnostic radiographic/fluoroscopic applications.
4. **Description of the Device:** Model R302DACS/A Automatic X-RAY Collimator is an Automatic X-ray beam-limiting system with a multilayer square field collimator. Stepper motors drive shutter movements as well as additional filters and the round field if these two features are mounted. A microprocessor circuit controls the stepper motors and provides the stepless adjustment of the square field dimensions at variable FFD (SID). The two stepper motors that provide shutter control may also be manually adjusted by the two knobs or by the pushbuttons located on the front panel. Two boards built into the collimator allow direct control of the system via CAN-Bus protocol.
5. **Safety and Effectiveness,** comparison to predicate device. The results of bench, safety test laboratory and user testing indicates that the new device is as safe and effective as the predicate device. The 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 R302DACS/A is as safe and effective as the predicate devices, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2007

Ralco SRL
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K072780

Trade/Device Name: Model R302DACs/A Automatic X-RAY Collimator
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam-limiting device
Regulatory Class: II
Product Code: IZW
Dated: September 26, 2007
Received: September 28, 2007

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 such 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Nancy C. Brogdon
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): K072780

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Indications For Use: Model R302DACS/A Automatic X-RAY Collimator is intended for use in diagnostic radiographic/fluoroscopic applications.

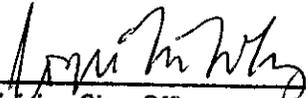
Prescription Use X
(Part 21 CFR 801 Subpart D)

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
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