510(k) Summary: K083029.

DEC 0 5 2008

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October 7, 2008
Contact person: Vincenzo Velardi, President and CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: Model R605DASM 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, K050092, Omega Medical Imaging, Inc Automatic Beam Limiting Device Model R605FACS .

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

4. **Description of the Device**: This device is a compact radiological automatic collimating system for round and elliptic fields designed to operate with a mobile "C" arm Image Intensifier equipment. The round and elliptical fields are defined as follows: The round field by 8 lead shutters located near the exit window and a brass cone near the x-ray focus; the elliptical field by the round field and two pairs of lead rectangular shutters located near the collimator entrance window. Round and elliptical field shutters are controlled by 5 stepping motors. The collimator features a microprocessor circuit built into the collimator to control the 5 stepping-motors via external signal source with CanBus protocol. The circuits return a CanBus protocol signal to indicate correct motor positioning. The two pairs of lead rectangular shutters move jointly and both rotate ± 360°..

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 device was made for Omega Medical Imaging and in fact carries virtually the same model name as the new Ralco 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 R605DASM 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC 0 5 2008

Re: K083029
Trade/Device Name: Model R605DASM 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: November 24, 2008
Received: November 25, 2008

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(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 Biometrics' (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,

Joyce M. Whang, Ph.D.
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): K083029

Device Name: Model R605DASM Automatic X-RAY Collimator

Indications For Use: Model R605DASM Automatic X-RAY Collimator is intended for use in diagnostic radiographic/fluoroscopic applications.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K083029