510(K) Summary, K093596

Lumos, Inc.
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JAN 12 2010

Date prepared: November 18, 2009

Contact person: James Whittaker, President and CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: Model R 72B Manual X-RAY Collimator
   Classification Name: collimator, manual, radiographic, Product Code KPW
   Common/Usual Name: Manual X-Ray Collimator.

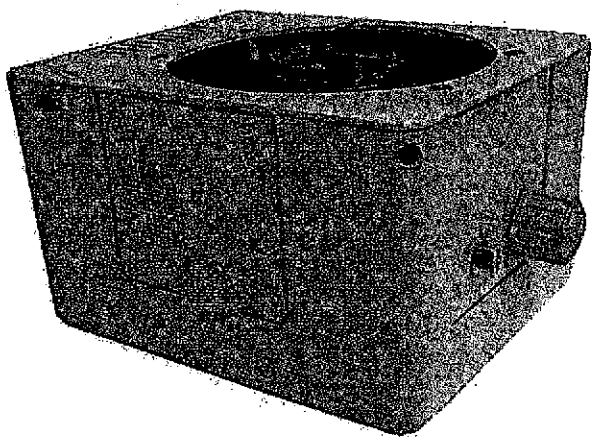
2. **Equivalent legally marketed devices:** This device is IDENTICAL to the Ralco Model R72 (K030487). This submission sets a baseline for Lumos Inc. to manufacture and control the design of the collimator shown in K030487..

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

4. **Description of the Device:** This is a compact collimator with an external cover in ABS plastic. It is a single-layer, square field radiological collimator. Its light weight and compact size allow easy positioning and make it ideal for mobile and portable units. The X-ray field size is limited by two pairs of lead shutters controlled by two knobs located on the sides of the collimator and by a lead disc near the x-ray focus to reduce scattered radiation. An indexed scale provides information on the field set with the knobs.

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. This device is identical to the predicate device made with the same components and specifications. 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 R 72B 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Lumos, Inc. (formerly Ralco, Inc.)
% Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
8726 Ferrara Ct.
NAPLES FL 34114

JAN 12 2010

Re: K093596
Trade/Device Name: Model R 72B Manual Collimator
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam-limiting device
Regulatory Class: II
Product Code: KPW
Dated: May 20, 2009
Received: November 25, 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K093596

Device Name: Model R 72B Manual Collimator

Indications For Use:

Model R 72B Manual X-RAY Collimator is intended for use in diagnostic radiographic or 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 K093596