K082921

FEB 17 2009

RAD SOURCE TECHNOLOGIES, INC.

6825 Shiloh Road East, Ste. B-2
Alpharetta, GA 30005
(770) 887-8669 email: info@radsource.com

510(k) Summary

Owner:

Rad Source Technologies, Inc.
6825 Shiloh Road East, Ste. B-2
Alpharetta, GA 30005
(770) 887-8669

Contact:

Randy Kirk, President

Device:

Trade name – RS 3400 Rad Source X-ray Blood Irradiator
Common name – Blood Irradiator
Classification name – N/A

Predicate Device:

RS 3000 Shielded Cabinet X-ray Radiation Source. **510(k) number K974210.**

Description of Device:

The RS 3400 Rad Source X-ray Blood Irradiator consists of a shielded enclosure containing one x-ray tube capable of emitting radiation in a 360 degree output around its cylindrical design, a power supply and controller. A carousel capable of holding 5 cylindrical containers rotates those cylinders around the cylindrical x-ray tube radiation source causing the blood products contained therein to be irradiated.

Intended Us of the Device:

The RS 3400 Rad Source X-ray Blood Irradiator is intended for the irradiation of blood or blood products packaged in transfusion bags in accordance with "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products" (22 July 1993 memorandum from Acting Director Office of Blood Research and Review, Center of Biologics Evaluation and Research, FDA to all registered blood

establishments) when irradiation to reduce the risk of Graft Versus Host Disease is indicated. This document is attached in Section 21 - Other.

Summary of Technological Characteristics of Device Submitted and Predicate Device:

The RS 3400 Rad Source X-ray Blood Irradiator is substantially equivalent to the RS 3000 Shielded Cabinet X-ray Radiation Source (K974210). Both are indicated for the irradiation of blood and blood products to reduce the risk of transfusion associated graft-versus-host disease in recipients at risk of this complication. The primary technological characteristic of both machines is the controlled production of X-ray radiation.

Characteristic	Submitted Device RS 3400	Predicate Device RS 3000
Source	150kVdc x-rays, .45 mm Cu filter, hvl app. H_2O cooled	160kVdc x-rays, .38 mm Cu filter, hvl app. 4 cm H_2O
Dose Rate	>5 Gy/minute	3 Gy/minute
Max/Min dose ratio:	<1.3	< 1.3
Sample holder:	Multiple holders in rotation around source, each canister fixes maximum irradiated volume	Fixed, presents maximum width, minimum depth
Radiation safety:	Pb shielding, interlocks	Pb shielding, interlocks
Federal Regulatory Environment	Requires 510(k). Must comply with 21 CFR 1020.4	Requires 510(k). Must comply with 21 CFR 1020.4

Non-Clinical Performance Data Used in Determining Substantial Equivalency:

The submitted device is indicated for the irradiation of blood and therefore the tests performed include measuring the radiation field resulting within the rotating containers when a blood product (using water as a sample) is contained within the rotating containers. The measured dose and field result in producing the necessary radiation to support the Indications for Use substantially equivalent to the predicate device.

Clinical Performance Data Used in Determining Substantial Equivalency:

None.

Conclusions Drawn from the Non-Clinical Tests:

Based on the Non-Clinical tests performed, it is concluded that the Submitted Device is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2009

Mr. Randol E. Kirk
President
Rad Source Technologies, Inc.
6825 Shiloh Road East, Suite B2
ALPHARETTA GA 30005

Re: K082921
Trade/Device Name: RS 3400 Rad Source X-ray Blood Irradiator
Regulation Number: None
Regulatory Class: Unclassified
Product Code: MOT
Dated: February 5, 2009
Received: February 9, 2009

Dear Mr. Kirk:

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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Manufactures, 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.suppot/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

K082921

Indications for Use

510(K) Number: (N/A) K082921

Device Name: RS 3400 Rad Source X-ray Blood Irradiator

Indications for Use:

Intended for the irradiation of blood or blood products packaged in transfusion bags in accordance with "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products" (22 July 1993 memorandum from Acting Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA to all registered blood establishments) when irradiation to reduce the risk of Graft Versus Host Disease is indicated.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K082921