



K974210

MAR 30 1998

**510(k) Summary  
as required by 807.92(c)  
for the RS 3000 Shielded Cabinet X-ray Radiation Source  
Prepared November 6, 1997**

Submitted by: Rad-Source, Inc..  
475 Ramblewood Dr. #207  
Coral Springs, Florida 33071  
Tel. 954 755-0328

Contact Person: Randol E. Kirk  
President

Device Trade Name: **RS 3000 Shielded Cabinet X-ray Radiation Source.**

Common Name: blood irradiator.

Classification: not classified.

Predicate Device: **IBL 437C (K865027)** manufactured by  
CIS-US, Inc.  
10 DeAngelo Drive  
Bedford, Massachusetts 01730

Description of Device:

The **RS 3000 Shielded Cabinet X-ray Radiation Source** consists of A shielded enclosure containing 2 vertically opposed x-ray tubes with provision for a sample holder (canister) between them, a power supply and a controller.  
(Brief physical description of the device and its function)

Intended Use of Device:

The **RS 3000 Shielded Cabinet X-ray Radiation Source** 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 for Biologics Evaluation and Research, FDA to all registered blood establishments) when irradiation to reduce the risk of Graft Versus Host Disease is indicated.



Substantial Equivalence to Predicate Device:

The **RS 3000 Shielded Cabinet X-ray Radiation Source** is substantially equivalent to the **IBL 437C Blood Irradiator** (K865027). 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 significant clinical characteristics of the two devices are compared below.

	<b>RS 3000</b>	<b>IBL 437C</b>
Source:	160 kVdc x-rays .38 mm Cu filter hvl app. 4 cm H <sub>2</sub> O	Cs-137, 662 keV
Dose rate:	3 Gy min <sup>-1</sup>	> 4 Gy min <sup>-1</sup>
Max/min dose ratio:	< 1.3	< 1.67
Sample holder:	fixed, presents maximum width, minimum depth	rotates in beam
Radiation safety:	Pb shielding, interlocks	Pb shielding, interlocks
Federal Regulatory Environment:	Requires 510(k). Must comply with 21 CFR 1020.40	Requires 510(k), user must have NRC license and radiation safety officer, operators must be film-badged.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 30 1998

Ronald E. Kirk  
Rad-Source, Inc.  
475 Ramblewood Drive, Suite 207  
Coral Spring, FL 33071

Re: K974210  
RS 3000 Shielded Cabinet X-Ray Radiation Source  
(Blood Irradiator)  
Dated: February 18, 1998  
Received: February 20, 1998  
Unclassified  
Procode: 90 MOT

Dear Mr. Kirk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

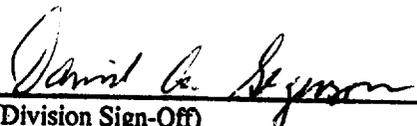
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

(For Indications for Use Statement and  
Section 8 of Premarket Submission Cover Letter)

**The RS 3000 Shielded Cabinet X-ray Radiation Source** 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 for Biologics Evaluation and Research, FDA to all registered blood establishments) when irradiation to reduce the risk of Graft Versus Host Disease is indicated.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K974210

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)