K030162

MAR 2 8 2003

510(k) Summary

Summary Date: January 13, 2003

Submitter Information: IsoRay, Inc.
350 Hills Street, Suite 106
Richland, WA 99352
Phone: 509-375-1202
FAX: 509-372-5153

Contact Person/Email: David J. Swanberg, COO
Email: DJSwanberg@msn.com

Trade Name: Lawrence CSERION Model CS-1

Common Name: Brachytherapy Sources (Seeds)

Classification Name: Class II, 90-KXK, Brachytherapy, Radionuclide

Primary Predicate Device: K924261 Radioactive Cesium-131 Seeds/Sources

Device Description: The IsoRay, Inc. Lawrence CSERION Model CS-1 is a small, cylindrical sealed source which contains the low energy gamma (X-ray) emitting radionuclide, cesium-131, adsorbed onto an internal inorganic substrate. The nominal external seed dimensions (4.5 mm length and 0.8 mm diameter) and patient-contacting material (titanium) are identical to predicate device(s).

Intended Use: IsoRay, Inc. Lawrence CSERION seeds are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors.

Comparison Chart:

Parameters for Evaluating Substantial Equivalence	IsoRay, Inc. Lawrence CSERION	Predicate Device(s)		
		K924261	K914281	K010283
Indications for Use	Malignant Disease	Same	Same	Same
Radionuclide	Cs-131	Same	I-125	Pd-103
Half-Life (days)	9.69	Same	59.4	17.0
Principle Energies (keV)	29.5, 29.8, 33.6	Same	27.4, 31.4, 35.5	20-22
Patient-Contacting Capsule:	Welded Titanium	Same	Same	Same
Nominal External Length (mm)	4.5	Same	Same	Same
Nominal External Diameter (mm)	0.8	Same	Same	Same
Radiographic Marker	Gold Wire	Various	Silver Rod	Lead Piece
Apparent Activity Range (mCi)	0.20 to 50.0	0.1 to 100	5.0 to 40	0.1 to 10
External Contamination (μCi)	< 0.005 μCi	Same	Same	Same
Implantation/Application Method	Needles, Applicators, Tubing, Catheters, Expanders, etc.	Same	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

Mr. David J. Swanberg
Chief Operations Officer
IsoRay, Inc.
350 Hills Street, Suite 106
RICHLAND WA 99352

Re: K030162
Trade/Device Name: Lawrence CSERION Model CS-1
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: January 13, 2003
Received: January 16, 2003

Dear Mr. Swanberg:

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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

D. Statement of Indications for Use

Applicant: IsoRay, Inc.

510(k) Number: K030162

Device Name: Lawrence CSERION Model CS-1

Indications For Use (Page 1 of 1):

IsoRay, Inc. Lawrence CSERION seeds are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The Counter Use ____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K03962