



NMSBZ

February 10, 2006

Mr. Thomas Thompson
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Amendment of License 06-30764-01
(Current Amendment No. 9) Docket No. 03036099

Dear Mr. Thompson

Advanced Care Medical is requesting that the referenced possession –storage packaging license be changed as follows

Item 6 : Add D. **Cesium 131**

Item 7: Add D. **Sealed Sources as specified in Condition 11**

Item 8: Add D. **130 curies total**

Item 11: Add

<u>Isotope</u>	<u>Source/Model #</u>	<u>Max Activity per Source</u>
CS-131	CSERION CS-1	130 mci internal activity

We have entered into an agreement with IsoRay, Richmond WA to utilize their sealed sources in our loose and stranded load configurations.

We are presently taking steps to implement ALARA principles and are increasing shielding in both our operational areas and in our final packaging. We have:

1. Designated three work stations and an Assay Station for extra shielding to process CS-131 sealed sources (See attached Room Layout for location)

115 HURLEY ROAD OXFORD, CT 06478
TEL: 203.262 4194 FAX: 203.262.4193

138410
NMSB/REG MATERIALS-002

REC'D IN LAT FEB 13 2006

2. Provided each of these work stations (tables) with additional lead shielding (2X the current thickness) underneath each table.
3. Provided each of these work stations with steel partitions at the front and sides of each work station.
4. Provided longer forceps/tools used for handling CS-131 seeds.
6. Established a policy of "operator rotation" when handling CS-131 sealed sources.
7. Relocated (8) operators who were stationed in the "restricted area" to another area in the facility. Although these operators wore dosimetry they did not work with radioactive material.
8. Ordered one additional area monitor to complement the six we are presently utilizing. The new monitor will be placed on a wall opposite the CS-131 work stations.

I am providing copies of the 510 (K) Summary ,provided by IsoRay (confirming the decision of the FDA to allow ISoRay to market their device) and the Sealed Source Device Safety Evaluation for their CS-1 sealed source. Attached is a copy of the current restriced area with projected locations for the four stations that will be utilizing CS-131.

IsoRay has been providing this device to hospitals for brachytherapy implants since October 2004.

Please contact me if you have any questions about this amendment request.

Sincerely,



Wayne W. Richardson
Radiation Safety Officer
Advanced Care Medical
Advanced Care Technologies
115 Hurley Road, Bldg. 3A
Oxford, CT 06478

510(k) Summary

K030162
MAR 28 2003

Summary Date: January 13, 2003

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

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-KXX, 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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 28 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 KXX
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.

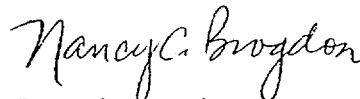
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

D. Statement of Indications for UseApplicant: IsoRay, Inc.510(k) Number: K030162Device Name: Lawrence CSERION Model CS-1Indications For Use (Page 1 of 1):

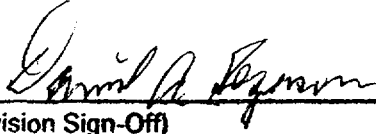
IsoRay, Inc. Lawrence CSERION seeds are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. The seeds may be used as a primary treatment or 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

K030162

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: WA-1220-S-101-S

DATE: 17 September 2004

PAGE: 1 of 8

SOURCE TYPE:

Sealed Brachytherapy Source

MODEL:

CS-1
Lawrence CSERION Cs-131 Brachytherapy Seed
(also known as 131Cseed)

DISTRIBUTOR:

IsoRay
Suite 106
350 Hills Street
Richland, WA 99352

MANUFACTURER:

IsoRay
Suite 106
350 Hills Street
Richland, WA 99352

ISOTOPE:

Cesium-131

MAXIMUMACTIVITY:

65 mCi (2.41 GBq) Internal Activity
2-5 mCi Average Air Kerma Strength/Assay Activity

LEAK TEST FREQUENCY:

Not Required

PRINCIPAL USE:

(AA) Manual Brachytherapy

CUSTOM SOURCE:

___ YES X NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: WA-1220-S-101-S

DATE: 17 September 2004

PAGE: 2 of 8

SOURCE TYPE:

Sealed Brachytherapy Source

DESCRIPTION:

The IsoRay Model CS-1 brachytherapy seed is a small, cylindrical, sealed source that consists of a welded titanium capsule containing the low energy gamma (X-ray) emitting isotope, cesium-131 ($T_{1/2} = 9.7$ d), 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 other commercially available brachytherapy sources for radiation oncology.

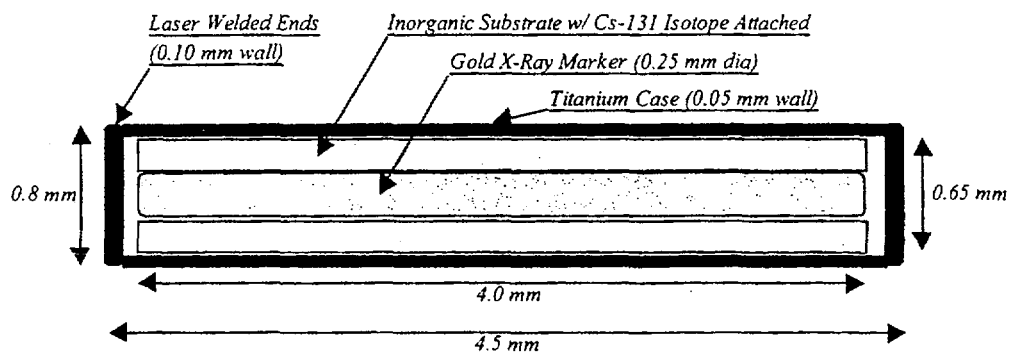
The brachytherapy seed contains a cylindrical inorganic substrate onto which a thin coating of radioactive cesium-131 is applied. A 0.25 mm diameter gold wire is placed within in the central annulus of the core. The gold wire serves as an X-ray marker for radiographic visualization of individual brachytherapy source locations. The internal core materials are inserted into a tube of commercially pure, grade 2 titanium (4.3 mm long, 0.8 mm OD, 0.7 mm ID). Titanium end caps (0.8 mm diameter, 0.1 mm thick) are precision laser welded in place.

LABELING:

Because of their small size, individual brachytherapy sources do not directly exhibit identifying marking, labeling or warnings. Multiple sources will be supplied in a primary container such as a glass vial or preloaded cartridges. The primary container will be placed inside a shielded storage container. The shielded storage container will be placed inside a shipping container meeting DOT requirements for shipment of radioactive materials. Examples of labels for each of these containers appear in Figures 1 – 3. The labels will be made of durable materials that remain legible during the expected conditions of transportation and use.

DIAGRAM:

A diagram of the IsoRay Model CS-1 brachytherapy seed showing components, dimensions, and the method of sealing appears below:



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: WA-1220-S-101-S

DATE: 17 September 2004

PAGE: 3 of 8

SOURCE TYPE: Sealed Brachytherapy Source

CONDITIONS OF NORMAL USE:

IsoRay Model CS-1 brachytherapy seeds are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) in a clinical setting and may be used in topical, 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.

Seeds are typically supplied non-sterile in radiation shielded packaging. The sources are capable of withstanding autoclave conditions. Sources may be implanted using any appropriate, FDA-approved device (e.g., 18-gauge brachytherapy needle, seed applicator, tubing, etc.). Radiological protection devices should be utilized during implantation procedures. When protective barriers are not practical, (e.g., certain surgical stages), the user must rely on time and distance to minimize radiation exposure.

PROTOTYPE TESTING:

IsoRay Model CS-1 Brachytherapy Seeds were classified and subjected to environmental test conditions and stresses as defined in ISO 2919-1999, "Radiation Protection – Sealed Radioactive Sources – General Requirements and Classification." The seeds successfully passed all of the required test conditions and are classified as ISO 99C53211, where the last five digits define the test conditions and requirements as shown in the following table. The cesium-131 isotope is classified as Group 3: Moderate Toxicity.

Test	Classification	Test Conditions
Low Temperature High Temperature	5	-40°C (20 min) w/ thermal shock to 20°C; +600°C (1 hr) w/ thermal shock to 20°C
External Low Pressure External High Pressure	3	Two 5 min periods at 25 kPa absolute; Two 5 min periods at 2 Mpa absolute
Impact	2	50 g steel weight dropped from 1 meter height
Vibration	1	No Test Required
Puncture	1	No Test Required
Bending	1	No Test Required
Steam Autoclave	Optional	121°C at 29.8 psig for 20 min

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: WA-1220-S-101-S

DATE: 17 September 2004

PAGE: 4 of 8

SOURCE TYPE: Sealed Brachytherapy Source

EXTERNAL RADIATION LEVELS:

The radiation dose rates in air at various distances from the Model CS-1 source were calculated using a gamma dose rate constant of 0.637 cGy/hr-mCi (637 mR/hr) at 1 cm. The dose rate constant is based on Air Kerma Rate measurements of actual seeds by the National Institute for Standards and Technology and has been confirmed using Monte Carlo calculations.

Distance from the source (cm)	Dose Rate (mR/hr) Maximum activity (50 mCi)	Dose Rate (mR/hr) Typical activity (3.3 mCi)
5	1300	84
30	35	2.3
100	3.2	0.21

QUALITY ASSURANCE AND CONTROL:

Prior to distribution, the following quality control tests will be completed:

Test	Method	Acceptance Criteria
Radionuclidic Purity	Gamma Analysis	> 99.9% Cs-131; < 0.01% Ba-131; < 0.1% Cs-132; < 0.05% all other radioisotopes
Weld Inspection	Visual - w/ Magnification	Silver in color, with no cracks or holes
Leak Test	ISO 9978	≤ 0.185 kBq (≤ 0.005 μ Ci) per seed
Radioassay	Dose Calibrator	0.2 to 50.0 mCi \pm 5% apparent activity
External Dimensions	Gauging	0.8mm \pm 10% OD; 4.5 mm \pm 10% length
Seed Assembly	Visual	No foreign material, dents, or scratches
Labeling	Visual	Information is legible, accurate and complete

IsoRay maintains a quality assurance program that is based on ISO 9001 requirements and is designed to comply with US Food and Drug Administration Quality System Requirements for medical devices. Elements of the quality system that are directly applicable to this brachytherapy seed are included in the application for safety evaluation of this sealed source.

This is to acknowledge the receipt of your letter/application dated

2/10/2006, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 06-30764-01 & 06-30764-02 MD
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 138410 / 138411
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.