Memorial
Medical Center
Member Conemaugh Health System

May 4, 2006

NM581

U.S.N.R.C.
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03003011

Re: License #37-01873-01

The purpose of this amendment application is to:

1. Add authorization to possess and use the low-dose-rate I-125 brachytherapy GliaSite Radiation Therapy system, with catheter models 1020, 1030, and 1040 using I-125 and sodium 3 – [I-125] iodo-4-hydroxybenzenesulfonate (I-HBS), from Proxima Therapeutics, Inc. The maximum activity of possession will not exceed 1320 millicuries. The procedure for use of this device is attached along with a copy of the Registry of Radioactive Sealed Sources and Devices.

2. Add authorization for Dr.'s Antemann and Stefanik to include the GliaSite Radiation Therapy System. Both physicians are currently on our radioactive materials license.

Thank you for your attention in this matter.

Sincerely,

Richard M. Sukenik
Vice-President
Conemaugh Valley Memorial Hospital

Enclosure

1086 Franklin Street
Johnstown, PA 15905-4398
814-534-9000
www.conemaugh.org

138885

NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

03003011

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [x] B. AMENDMENT TO LICENSE NUMBER 37-01873-01
- [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Conemaugh Valley Memorial Hospital
1086 Franklin Street
Johnstown, PA 15905-4398

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Keith Ostrom,Consultant, Associates in Medical Physics, LLC

TELEPHONE NUMBER

(216) 663-7000

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY N/A | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE AP PLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURIS DICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
RICHARD M. SUKEN, K, VP		5/8/06

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

Conemaugh Valley Memorial Hospital
Johnstown, PA

PROCEDURES FOR GLIASITE® (IOTREX® 1-125)
RADIATION THERAPY SYSTEM

1. All procedures and instructions specified in the **GliaSite Radiation Therapy System Instruction Manual** of Proxima Therapeutics, Inc. will be followed except as specified in this letter.

2. Total activity will be included in the"'written directive."

3. The dosage will be assayed based on the procedure of Technical Information Bulletin No. 1 **The** Assay **of Iotrex (1-125 Radiotherapy Solution)** of Proxima Therapeutics, Inc.

4. The treatment team shall consist of the authorized user (Radiation Oncologist), a Neurosurgeon and either the Medical Physicist or Radiation Safety Officer (RSO). This team will be physically present during all the procedures of Iotrex administration and retrieval. The authorized user will undergo product specific training provided by Proxima Therapeutics, Inc. If any technologists participate in these treatments, they will also complete the manufacturer's training program.

5. In view of the inherent problems associated with the collection of urine and analysis at 24 our intervals, we will demonstrate instead that the GliaSite device has not leaked as follows:

   a. Radiation exposure will be measured at a fixed distance, say 10 cm, from at least three cranial landmarks immediately after the infusion of Iotrex and at least once daily thereafter for the duration of treatment. If any two of the measurements indicate a drop of more than 20% from the initial reading, it will be reported to the RSO. The RSO will investigate and report the result to the vendor and the NRC within 24 hours by telephone.

   b. Daily exposure measurements over the patient's bladder will also be done. According to Proxima, the typical background level is about 0.1 mR/hr over the bladder. If any bladder reading exceeds five times the typical background level, the RSO will investigate and if it suggests the possibility of more than 1% leakage of the infused activity, Proxima and the NRC will be notified within 24 hours by telephone.

c. The total Iotrex fluid volume retrieved from the GliaSite device after treatment will be measured. If the fluid volume is less by 20% or more compared to the infused volume, the RSO will investigate and notify Proxima and the Bureau of Radiation Protection within 24 hours by telephone. The Iotrex device after retrieval from the patient will be visually examined for signs of rupture or leakage. Proxima and the NRC will be notified in case of any such occurrence.

d. For the first five patients treated, measurements will be carried out to evaluate the amount of radioactivity contained in the fluid collected during retrieval. A small volume of the Iotrex solution (approximately 2 ml) will be collected in a 5 ml syringe to remove the saline used to prime the extension tube. An aliquot of 2-3 ml will then be collected in a 5 ml syringe. The remainder of the Iotrex solution from the GliaSite balloon will be retrieved in a 20 ml syringe. The activity of the Iotrex in the 5 ml syringe will be measured in a dose calibrator using the correction factor supplied by Proxima yielding the concentration in mCi/ml. The total activity that was retrieved will then be calculated from the total volume retrieved from the balloon. If the total activity calculated differs by more than 20% from the administered activity, Proxima and the NRC will be notified by telephone.

6. Regulatory obligations and those of our license application will be followed for the possession and use of unsealed radioactive material and brachytherapy sources.

7. Surveys will be performed on equipment/surgical instruments used for the infusion/retrieval of the catheter. The survey meter used will be suitable for the detection of low energy gamma radiation. The implantation device and any item contaminated will be stored as radioactive waste.

8. Persons who will care for the patient will be instructed to pay particular attention to dressings and linen around the catheter for leakage during the treatment.

9. Iotrex contains Sodium 3-(1-125) iodo-4-hydroxybenzene-sulfonate (I-125 - HBS) and is nonvolatile. Air sampling monitoring of administration and retrieval processes of Iotrex solution in bench top settings resulted in airborne concentrations of 300 times less compared to USNRC regulatory limits for Derived Air Concentration (DAC) for I-125 **(Frequently Asked Questions Related to Iotrex Usage**, March 13, 2001, Proxima Therapeutics, Inc.). Further, according to the **Technical Information Bulletin No. 3,** no individual tested for bioassay at different centers involved in GliaSite therapy with Iotrex demonstrated additional thyroid uptake of 1-125 above background. According to the information from Proxima, thyroid bioassay is not a requirement for the NRC licensees using this

device and we, therefore, request an exemption from thyroid bioassay of personnel involved in the administration and retrieval of the Iotrex.

10. All items in the patient's room will be monitored for possible contamination. Contaminated items will be considered as radioactive waste.

11. No patient will be released until Iotrex and the GliaSite catheters have been removed and the surveys confirm there is no contamination.

12. The retrieved Iotrex solution, the GliaSite device, and any other contaminated items will be handled as radioactive waste.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: GA-1148-D-I01-S **DATE:** September 11, 2001 **PAGE:** 1 of 12

DEVICE TYPE: Low Dose Rate Brachytherapy

MODEL: GliaSiteR RTS System, with catheter Models 1020, 1030, and 1040

MANUFACTURER/DISTRIBUTOR:

Proxima Therapeutics, Inc.
2555 Marconi Drive
Suite 220
Alpharetta, Georgia 30005-2066

RADIONUCLIDE FORM AND DESCRIPTION:

Iotrex, a proprietary liquid solution, consisting of a combination of iodide and sodium 3-[I-125] iodo-4-hydroxybenzenesulfonate (I-HBS)

ISOTOPE:	MAXIMUM ACTIVITY:
Iodine-I25	1320 millicuries (48.84 GBq), [1200 mCi (44.4 GBq) + 10%]

LEAK TEST FREQUENCY: Not Required – device is single use and is never implanted for greater than 6 months

PRINCIPAL USE: (M) General Medical Use

CUSTOM DEVICE: - Y E S X N O

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Low Dose Rate Brachytherapy

DESCRIPTION:

The GliaSite RTS System is a single-use low-dose rate brachytherapy system consisting of a double-wall balloon catheter filled with Iotrex, a solution containing organically bound I-125. The system is intended to deliver intracavity radiation therapy in patients with malignant brain tumors following tumor resection surgery. Radiation therapy is delivered by inflating the balloon portion of the device with a combination of Iotrex solution and saline. After a patient-specific dwell time, the Iotrex solution is removed from the catheter, and the catheter is then removed from the patient.

The GliaSite catheter is constructed from common biocompatible materials and is configured similar to other currently marketed interstitial and intracavity brachytherapy applicators.

The GliaSite catheter consists of a shaft with an inflatable dual silicon balloon configuration (balloon within a balloon) at the distal (treatment) end and an infusion port at the proximal end. The three models of the GliaSite catheter refer to different sized balloons, and thus, different fill volumes. The balloon diameters and maximum inflation volumes are contained in the table below.

Catheter Model	Balloon Diameter	Maximum Fill Volume
1020	2 cm	5 mL
1030	3 cm	15 mL
1040	4 cm	35 mL

The inner balloon acts as a reservoir for the Iotrex solution. The outer balloon serves as the backup reservoir in the event the inner balloon ruptures. The catheter shaft is constructed from radiopaque silicone, bi-lumen tubing and contains a malleable titanium element to assist in positioning of the balloon. Both ends of the inner balloon have radiopaque markers along the catheter shaft. Additionally, the catheter shaft is equipped with positioning markers at 1 cm intervals beginning from the proximal end of the balloon.

The primary catheter lumen, which is used to access the inner balloon, is connected to the infusion port. To prevent leakage during insertion of the Iotrex solution, the infusion port is equipped with a self-sealing silicone septum.

Refer to Figure 1 for a picture of an inflated, 3cm diameter GliaSite catheter.

Refer to Figures 2-4 for a simplified step-by-step walk through of a typical GliaSite treatment, showing how the GliaSite is implanted and Iotrex is inserted.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Low Dose Rate Brachytherapy

LABELING:

The GliaSite catheters do not require standard radioactive materials labeling since (1) the catheters, when shipped, do not contain radioactive material; (2) the only time the catheter contains radioactive material is when it is implanted in the patient; (3) radioactive material is removed from the catheter prior to removal from the patient; and (4) the catheter is disposed of as radioactive waste or decayed in storage.

The catheter itself is marked with "PROXIMA" and the model number of the catheter.

The tray in which the catheter is provided, as well as the box in which the catheter and its ancillary equipment is shipped, is labeled in accordance with FDA guidelines. A sample label for the GliaSite box is provided in Figure 5.

A sample of the labels on the Iotrex solution vial and shipping container is provided in Figures 6 and 7.

DIAGRAM:

Figure 1	--	inflated GliaSite catheter
Figure 2	--	shows tumor resection cavity
Figure 3	--	shows placement of GliaSite catheter into resection cavity
Figure 4	--	shows infusion of Iotrex solution
Figure 5	--	sample GliaSite box label
Figure 6	--	sample Iotrex vial label
Figure 7	--	sample Iotrex shipping container label

CONDITIONS OF NORMAL USE:

The GliaSite catheters are sterilized and stored in sealed containers prior to use. The catheter is inserted into the patient during surgery and the balloon is inflated. The entire catheter will be enclosed within the patient during the treatment time. The infusion port is located beneath the skin.

The Iotrex solution is received at the facility within 48 hours of its intended use in unit dose vials of not less than 150 millicuries. The Iotrex is withdrawn from the vials into a syringe and injected into the GliaSite catheter via the infusion port in the patient's private room or other secured location. Removal of the Iotrex is accomplished by reversing the insertion procedure.

Both the GliaSite catheter and the Iotrex solution are single use and are disposed of as radioactive waste upon removal from the patient.

DEVICE TYPE: Low Dose Rate Brachytherapy

PROTOTYPE TESTING:

The GliaSite catheter has been subjected to a battery of tests to confirm its integrity in typical use and expected accident conditions. These tests included bend and tensile testing of the catheter shaft, design pressure verification of the balloons, material interaction of the balloon (with x-ray contrast solution, saline, and Iotrex), and the ability to successfully image the catheter.

Since the GliaSite catheter must withstand gamma sterilization in the mega-Rad range prior to use, additional testing of the effects of the radiation emitted from the Iotrex is not required.

Standard leak test methods for sealed sources cannot be used on GliaSite. Instead, the GliaSite is evaluated based on the amount of pressure the balloon can withstand, and the amount of liquid that will permeate across the balloons over an extended period of time. It has been confirmed during animal and clinical trials that, because of silicon's permeability to small molecules, approximately 1% of the afterloaded activity will diffuse across the membrane into the body. This has been evaluated and determined to have no adverse effects on the patient. Uptake in the thyroid gland can be minimized by administering a thyroid-blocking agent to the patient prior to implantation.

The makeup of the Iotrex compound is such that it precludes uptake into the body or its organs. To simulate a catheter failure (both balloons rupture and release the Iotrex), Iotrex was injected directly into the brain and tracked through the body. At 2 hours following injection, 93% had been excreted from the body; at 4 hours, 97.2% of the initial activity had been excreted. This shows that Iotrex is removed from the body quicker than standard radio-iodide, which has a biologic half-life of 8 hours.

To date, clinical trials using the GliaSite RTS have utilized a maximum activity of 450 mCi of Iotrex. Data has shown that the GliaSite catheter can safely handle up to 1200 mCi of Iotrex.

The GliaSite catheter has a shelf life of 5 years from the date of manufacture. It has undergone accelerated aging tests to validate that this shelf life will not adversely affect product performance or safety.

The Iotrex solution has a shelf life of 19 days based on the specification that no more than 20% of the I-125 can be in a non-bound (iodide) form at the time of afterloading. The amount of non-bound I-125 increases over time as the I-HBS compound breaks down.

EXTERNAL RADIATION LEVELS:

The manufacturer provided calculated exposure rates from the head of a patient who received a GliaSite treatment with 1200 mCi of Iotrex. Additionally, the manufacturer provided actual data collected during trials for patients who received GliaSite treatments with up to 460 mCi of Iotrex. There is no direct correlation between administered activity and exposure rates around the patient because (1) the location of the GliaSite catheter with respect to the surface of the head varies from patient to patient; and (2) the physical makeup of the patient (i.e., skull thickness and skin thickness) varies, resulting in different levels of radiation attenuation.

DEVICE TYPE: Low Dose Rate Brachytherapy

EXTERNAL RADIATION LEVELS: (continued)

The exposure rates around a patient are recorded in the table below.

	Exposure Rate, mR/hr [μSv/hr]		
Distance from Patient's Head	**calculated (1200 mCi)**	**clinical range (up to 460 mCi)**	**typical expected (up to 460 mCi)**
5 cm **	4310 [43,100]	20 – 650 [200 – 6500]	200 [2000]
30 cm	206 [2060]	not reported	not reported
100 cm	20 [200]	0.2 – 3.4 [2 – 34]	2 [20]
at room doorway	not calculated	0.02 – 0.6 [0.2 – 60]	< 0.1 [< 1]

** exposure rates were recorded at surface of head in clinical trials

QUALITY ASSURANCE AND CONTROL:

The manufacturer has implemented a Quality System that meets the qualifications of ISO 9001:1994, EN46001, and 21 CFR Part 820 (Quality Systems Regulations), which encompasses FDA's Current Good Manufacturing Practices.

Items that are provided by suppliers or subcontractors must conform to the design controls and specification requirements of the manufacturer's Quality System. The design controls provide evidence of device performance, verification and validation through all phases of use, and indicate the QC checkpoints during component construction.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The GliaSite RTS System shall be distributed to persons specifically licensed for the use of radioactive materials in the healing arts by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The GliaSite RTS System shall only be used under the supervision of an authorized user, or as approved by the U.S. Food and Drug Administration (FDA).
- Users of the GliaSite RTS System shall have completed initial training by the manufacturer, or person specifically licensed by the NRC or an Agreement State to provide such training, prior to initial use.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Low Dose Rate Brachytherapy

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: (continued)

- The Iotrex solution has not had a sealed source evaluation performed on it because, being a liquid, it cannot meet the requirements for a sealed source. Iotrex solution has been deemed acceptable for use in the GliaSite RTS System.
- It is recommended that patients who will be administered Iotrex in the GliaSite RTS System also be administered a thyroid blocking agent in accordance with the precautions set out in the GliaSite RTS Instruction Manual.
- REVIEWER NOTE: Care should be taken during insertion and removal of Iotrex to minimize the potential of surface contamination of the patient.
- REVIEWER NOTE: Patients who have been administered Iotrex in the GliaSite RTS System can be monitored and handled as if they were undergoing a thyroid ablation. For example, the product information insert for Iotrex recommends, "...all clothing, bandages or linens that come into contact with urine, sweat, or saliva should be surveyed for the presence of ^{125}I." Following those procedures will adequately protect workers and the general public from radiation coming from the patient.
- REVIEWER NOTE: Facilities might want to consider the placement of the bed in the patient's room so that doses emanating from patient's head do not have an impact on workers and unrestricted areas.
- REVIEWER NOTE: A radioactive spill kit should be available in the room in the event of a radioactive spill and personnel should be trained for its use.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Georgia Department of Natural Resources, Radioactive Materials Program.

SAFETY ANALYSIS SUMMARY:

The GliaSite RTS System delivers a radiation therapy to the resected cavities of brain tumors. The GliaSite catheter remains in a sterile package until implanted in the patient following tumor resection. The system is radioactive only after the Iotrex solution is injected into the GliaSite catheter, which has been previously implanted and completely contained within the patient's body. The Iotrex solution, shipped within 48 hours of expected use, is contained within a double walled balloon catheter that has been shown to be compatible with the body and also to maintain its integrity while the therapy is delivered.

Both the GliaSite catheter and the Iotrex solution are single use and are disposed of as radioactive waste upon completion of treatment.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Low Dose Rate Brachytherapy

SAFETY ANALYSIS SUMMARY: (continued)

Under normal use, the GliaSite catheter is expected to release 1% of the loaded activity into the body because of the permeability of silicon to small molecules. This has been evaluated by the FDA and determined to have no adverse effects on the patient.

In the unlikely event that a GliaSite catheter fails during treatment and releases the Iotrex into the body, the Iotrex will be rapidly removed from the body primarily through the urine. Using the maximum dose administered to date, 460 mCi, doses to vital organs under this scenario are less than those received during a routine thyroid ablation using 150 mCi of I-131. To protect the patient in the event of device failure, a thyroid-blocking agent should be administered prior to implantation and during the course of treatment as outlined in the precautions in the GliaSite RTS Instruction Manual.

Based on review of the GliaSite RTS System, and the information and test data cited below, we conclude that the device is acceptable for licensing purposes. Furthermore, we conclude that the GliaSite RTS System would be expected to maintain its containment integrity for normal conditions of use and accidental conditions that might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the GliaSite RTS System are hereby incorporated by reference and are made a part of this registry document.

- Proxima Therapeutics, Inc.'s application with enclosures dated March 6, 2001, and signed by James B. Stubbs, Ph.D., Vice President, Scientific Affairs.
- Letter with enclosures dated August 6, 2001 and, signed by James B. Stubbs, Ph.D., Vice President, Scientific Affairs.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO. GA-1148-D-101-S **DATE:** September 11, 2001 **PAGE:** 8 of 12

DEVICE TYPE: Low Dose Rate Brachytherapy

ISSUING AGENCY: Georgia Department of Natural Resources
Radioactive Materials Program

This document is not a license to receive, possess or distribute radioactive material. Receipt, possession and distribution of radioactive material, sources and devices containing radioactive material, are subject to the terms and conditions of applicable regulations and licenses issued by NRC or Agreement States.

Date: September 11, 2001 Reviewer: Eric T. Jameson

Date: 11 September 2001 Concurrence: Elizabeth L. Drinnon

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO. GA-1148-D-101-S **DATE:** September 11, 2001 **Attachment 1**

Figure 1. An inflated, 3-cm diameter GliaSite

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO. GA-1148-D-101-S **DATE:** September 11, 2001 **Attachment 1**

Figure 1. An inflated, 3-cm diameter GliaSite

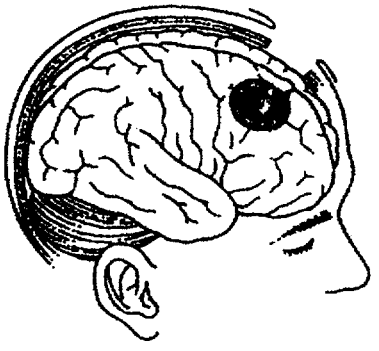


Figure 2 . Malignant tumor is resected leaving behind the resection cavity.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO. GA-1148-D-101-S **DATE:** September 11, 2001 **Attachment 2**

Figure 3. Surgical placement of the deflated GliaSite into the surgical resection cavity. The infusion port is also placed subcutaneously.

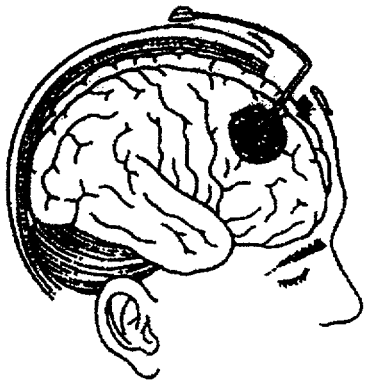
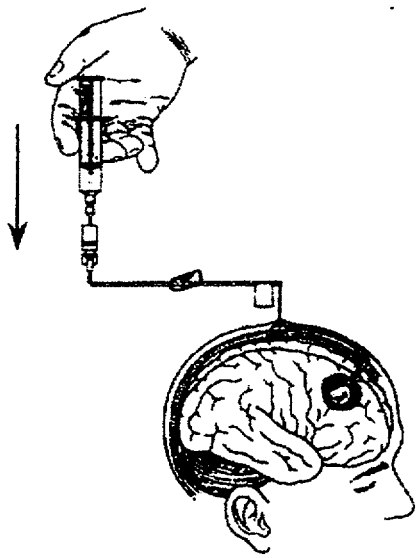


Figure 4. Iotrex is infused into a deflated GliaSite through the infusion set. An absorbent drape covers the patient's head during infusion and retrieval procedures (not shown).



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO. GA-1148-D-101-S **DATE:** September 11, 2001 **Attachment 3**

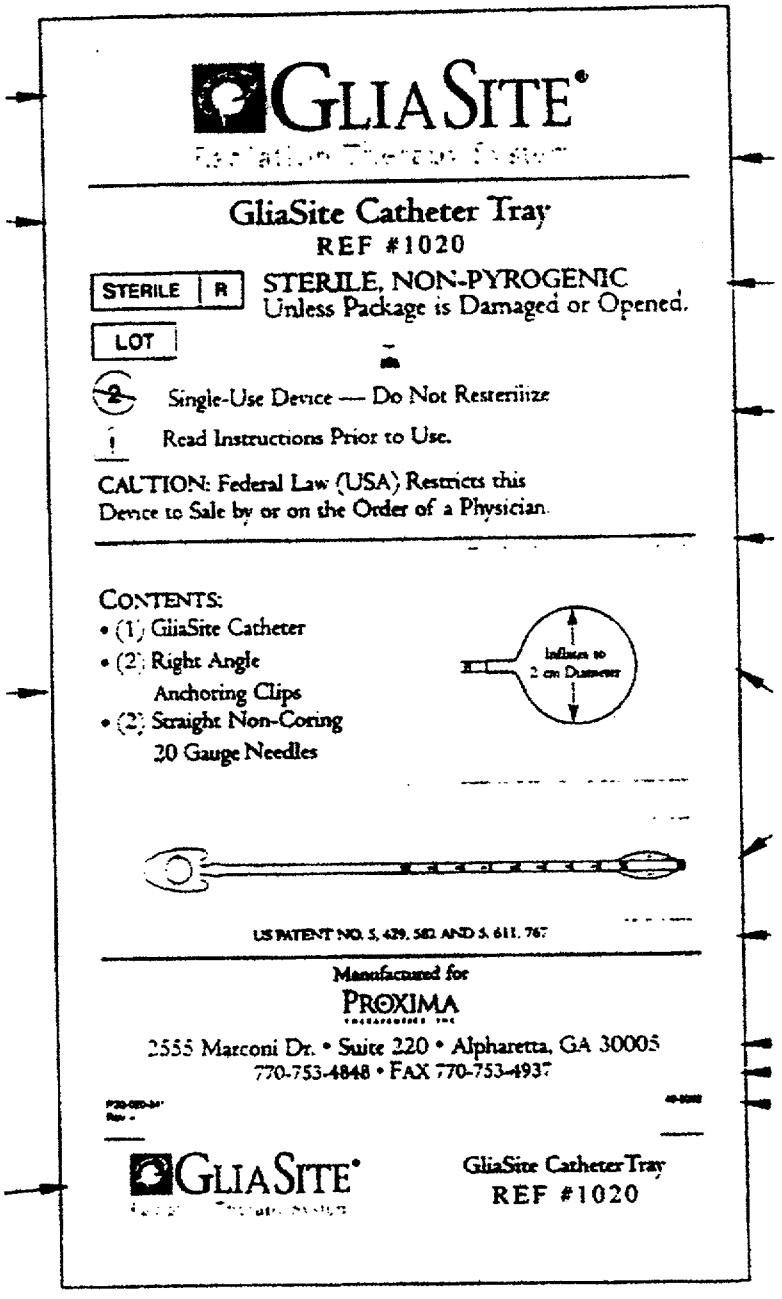


Figure 5 – GliaSite box label

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO. GA-1148-D-101-S **DATE:** September 11, 2001 Attachment 4

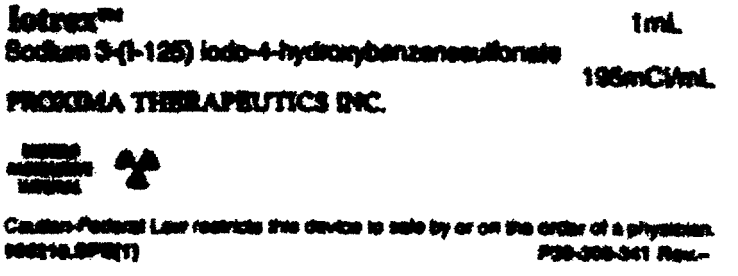


Figure 6 – Iotrex vial label

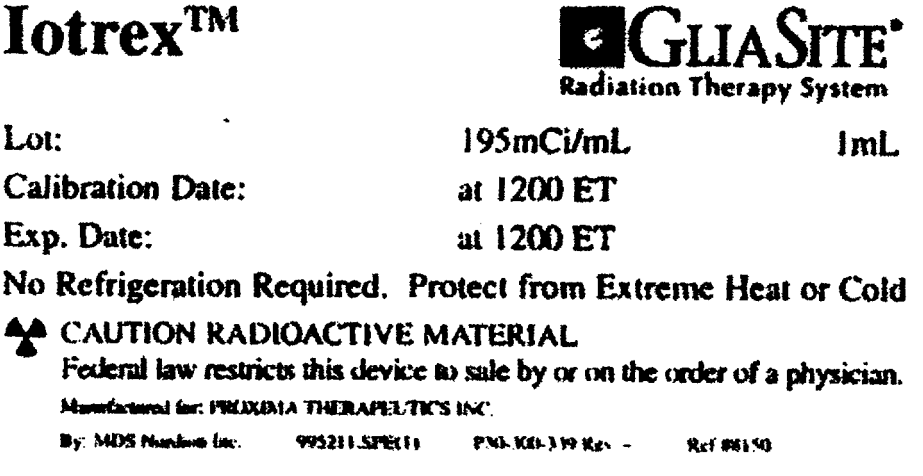


Figure 7 – Iotrex shipping container label

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

5/4/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☑ 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. 37-01873-01 AMENDMENT

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

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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** 138885.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader