MAY 13 1999

K982226

510(k) Summary of Safety and Effectiveness
UroMed Brachytherapy Iodine-125 Sources

Company Name

UroMed Corporation
64 A Street
Needham, MA 02194

Official Contact

Nancy MacDonald
Manager, Clinical and Regulatory Affairs

Device Name

Proprietary Name:	UroMed Brachytherapy Iodine-125 Sources
Common Name:	Brachytherapy Iodine-125 Sources
Classification Name(s):	21 CFR 892.5730 Radionuclide Brachytherapy Source

Predicate Devices used for Substantial Equivalence

Device	Premarket #
Amersham I-125 Seeds in Absorbable Carrier (formerly marketed by 3M Co.)	K801748
North American Scientific I-125 Radionuclide Brachytherapy Sources	K972271
North American Scientific I-125 Radionuclide Brachytherapy Sources	K964647
Theragenics Modified Paladium Seed	K874787

Intended Use

The UroMed Brachytherapy Iodine-125 Sources are intended for use in the treatment of cancer with radioactive sources in close proximity to or within the tumor.

Indications for Use

The UroMed I-125 Radionuclide Brachytherapy Sources are indicated for the treatment of selected localized tumors. These sources are commonly used to treat superficial, intra-abdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas and prostate are commonly treated. They may be used alone, or in combination with external beam radiation.

Description

UroMed I-125 Sources are cylindrical sealed sources containing iodine-125 radioactivity. The sources are 4.5mm long and 0.8mm in diameter. The outer capsule of the source is composed of titanium, and is sealed at each end by a laser weld. The iodine-125 is deposited within a porous ceramic tube as silver iodide (AgI). A radiopaque marker is located in the center of the ceramic tube to serve as an x-ray marker. The marker will be composed of gold alloy or iridium.

Iodine seeds have a half-life of 59.6 days and are available in a range of activity levels. The UroMed I-125 Sources are provided non-sterile and must be sterilized prior to use.

Summary of Standards Achieved

FDA Quality System Regulation 21 CFR Part 820 Good Manufacturing Practice.

ISO 46001: Quality System

ISO 10993-1: 1992 (E), "Biological Evaluation of Medical Devices".

ASTM Standard for Titanium: F136-96e; Titanium alloy ASTM Grade 5 6AI-4V ELI Electro low interstitial elements.

ANSI Standards for Brachytherapy:
N44.1 – 1973: "Integrity and Testing Specifications for Selected Brachytherapy Sources."
N44.2 – 1973: "Leak Testing Radioactive Brachytherapy Sources."

ISO 9978: 1992(E), "Radiation protection – Sealed radioactive sources – Leakage test Methods".

AAMI document, "Recommended Practice for Determining Residual Ethylene Oxide in Medical Devices".

Summary

In summary, the UroMed I-125 Radionuclide Brachytherapy Sources are substantially equivalent to legally marketed devices. Quality System Controls assure the device is substantially equivalent to the predicate devices with respect to its performance, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1999

Frederick Tobia
Director, Clinical And Regulatory Affairs
UroMed Corporation
1400 Providence Highway, Bldg. 2
Norwood, MA 02062

RE: K982226
UroMed Brachytherapy Seeds
Dated: February 17, 1999
Received: February 18, 1999
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Mr. Tobia:

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
UroMed Brachytherapy Iodine-125 Sources

510(k) Number (if known): K_____

Device Name: UroMed I-125 Radionuclide Brachytherapy Sources

Indication for Use:

The UroMed I-125 Radionuclide Brachytherapy Sources are indicated for the treatment of selected localized tumors. These sources are commonly used to treat superficial, intra-abdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas and prostate are commonly treated. They may be used alone, or in combination with external beam radiation.

(PLEASE 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)

David A. Clegerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982226