

Summary of Safety and Effectiveness
for
¹²⁵I Brachytherapy Seeds

MAR 14 2000

submitted by
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K993280

Identification of Device

Classification Name: Radionuclide brachytherapy source
Common/Usual Name: ¹²⁵I Radioactive Seeds
Proprietary Name: Prostec ¹²⁵I Brachytherapy Seed
Classification: Class II, classification number is 90KXX

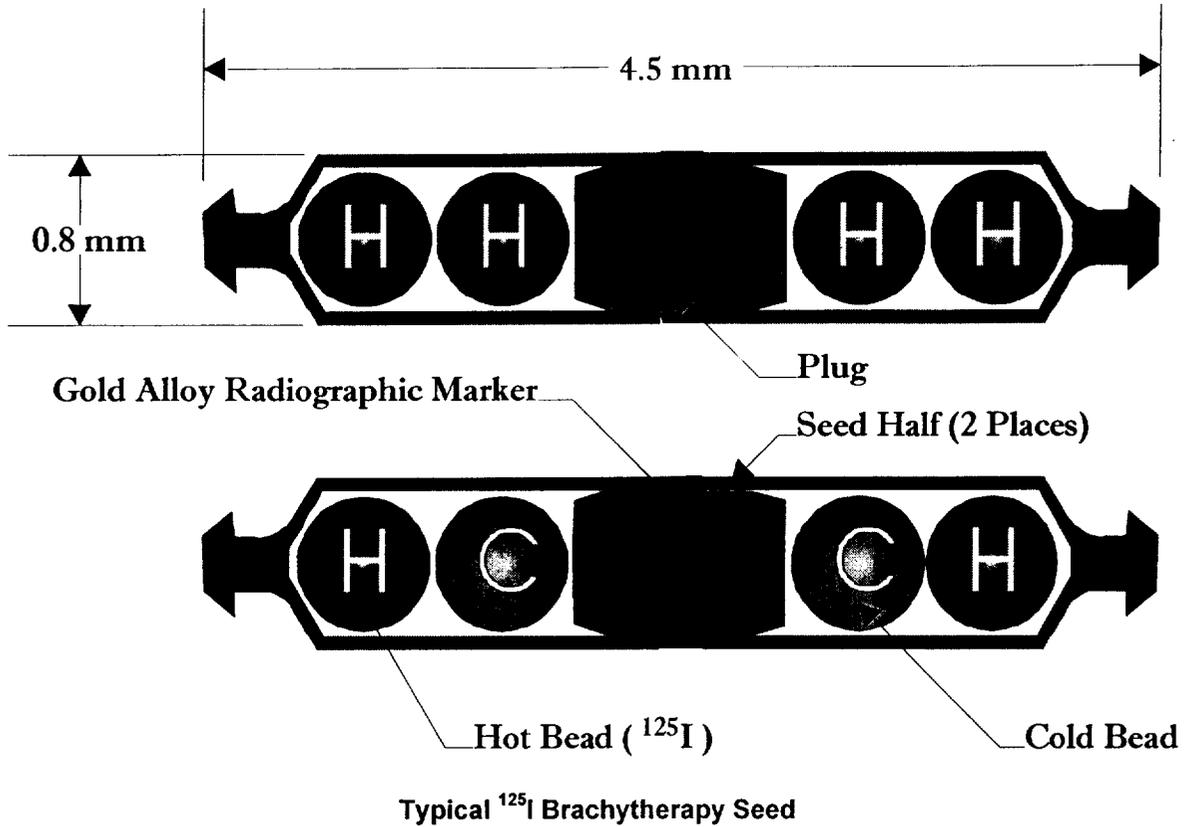
Identification of a Legally Marketed Predicate Device

The Prostec LLC ¹²⁵I Brachytherapy Seeds are substantially equivalent to the Amer-sham/Medi+Physics Model 6702 seeds, which are legally manufactured and distributed pursuant to 510(k) K915156.

Device Description

The ¹²⁵I Brachytherapy Seeds consist of ¹²⁵I absorbed onto the surface of a spherical polymeric substrate sealed in a welded titanium casing. A typical Brachytherapy Seed is shown below. For higher activity levels the number of beads with absorbed ¹²⁵I may be increased from 2 to 4.

Typically, the ¹²⁵I Brachytherapy Seeds are placed within or in close to the tumor to be treated utilizing guidance. The devices are delivered using an 18 gauge or greater diameter hypodermic needle.



Intended Use

¹²⁵I Brachytherapy Seeds are intended for permanent interstitial implantation in selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

Summary of Technological Characteristics

The table below compares the technological characteristics of the ¹²⁵I Brachytherapy Seeds to the predicate device.

Feature	¹²⁵ I Brachytherapy Seeds	Predicate Device
Manufacturer	Prostec LLC	Amersham/Medi+Physics
510(k) Number	To be determined	K915156
Delivered Non-sterile	Yes	Yes
Intended use	¹²⁵ I Brachytherapy Seeds are intended for permanent interstitial implantation in selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.	¹²⁵ I seeds are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity.

Feature	¹²⁵ I Brachytherapy Seeds	Predicate Device
Capsule	Titanium	Titanium
Capsule Sealing Method	Laser Weld	Weld
Radioisotope	¹²⁵ I	¹²⁵ I
Half-life	59.4 days	59.4 days
Principal Energy Levels (keV)	27.4, 31.4, and 35.5	27.4, 31.4, and 35.5
¹²⁵ I Substrate	Dowex®	Dowex®
Radiographic Marker	Gold Alloy	None
Packaging	Glass vial in lead container placed in a shipping carton	Glass vial in lead container placed in a shipping carton
Length	4.5 mm	4.5 mm
Outside Diameter	0.8	0.8
Application Methods	Through an 18 gauge needle, needle may be attached a Mick applicator provided that the Prostec Cartridge is used.	Through an 18 gauge needle, needle may be attached to common applicators such as the Mick, Henschke, or Scott
Apparent Activity Level	0.1 to 5.0 mCi	5.0 to 40 mCi
Point-source approximation anisotropy constant $\bar{\phi}_{an}$	0.96	0.95
Dose rate Constant $cGy/hr/U$, 1999 NIST	1.05	1.04
Seed Strength Specification	Apparent activity in mCi and air-kerma	Apparent activity in mCi and air-kerma
Residual Activity	< 0.2 μ Ci after 2 years	< 0.2 μ Ci after 2 years

Summary of Performance Data

The ¹²⁵I Brachytherapy Seeds comply with the following standards, practices, and guidances:

- ISO 2919-1980(e), *Sealed radioactive sources — Classification*, International Organization for Standardization, First Edition (1980)
- ISO/TR 4826-1979(E), Technical Report 4826: *Sealed radioactive sources — Leak test methods*, pg 2, International Organization for Standardization (1979)

The tissue contact materials of the ¹²⁵I Brachytherapy Seeds meet the requirements of the following recognized consensus standards.

- ASTM F 1472 – 93, Standard Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications.
- ASTM F 67 – 95, Standard Specification for Unalloyed Titanium for Surgical Implant Applications.

The anisotropy of the ¹²⁵I Brachytherapy Seeds and the Amersham/Medi+Physics I-125 were compared and found to be equivalent. The ¹²⁵I Brachytherapy Seeds are substantially equivalent to the Amersham/Medi+Physics Model 6702 seeds, which are legally manufactured and distributed pursuant to 510(k) K915156. This has been demonstrated by comparison of physical characteristics, dimensional measurements, and anisotropy.

Brachytherapy is an old and well-established medical treatment. ¹²⁵I is a well-characterized radioactive source for brachytherapy treatment. The use of ¹²⁵I is has been documented by B. C. Hilaris, D. J. Holt and J. St. Germain in FDA Report 76-8022.†

Since the ¹²⁵I Brachytherapy Seeds meet the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The ¹²⁵I Brachytherapy Seeds will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

† Hilaris BC, Holt DJ, St. Germain J: *Use of Iodine ¹²⁵I Radioactive Seeds for Interstitial Implant*



MAR 14 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Al Weisenborn
Prostec LLC
19526 East Lake Drive
Miami, FL 33015Re: K993280
Prostec ¹²⁵I Brachytherapy Seeds
Dated: January 6, 2000
Received: January 7, 2000
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXX

Dear Mr. Weisenborn:

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

Indications for Use

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510(k) Number (if known): K993280

Device Name ¹²⁵I Brachytherapy Seeds

Indications for Use:

¹²⁵I Brachytherapy Seeds are intended for permanent interstitial implantation in selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segorin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993280

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)