K081066

MAY 15 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following 510(k) Summary of Safety and Effectiveness is prepared and provided in accordance with the requirements of 21 CFR 807.92 as amended under the Safe Medical Devices Act of 1990 (SMDA).

Submitter's Information

Company Name:	Medi-Physics, Inc DBA GE Healthcare
Address:	101 Carnegie Center Princeton, NJ 08540-6231
Contact Name:	David Risley Director, US Regulatory Co-ordination Group Regulatory Affairs
Phone Number:	609-514-6489
Summary Prepared Date:	April 3, 2008

Subject Device Information

Trade Name:	Brachytherapy Source Device
Model:	9011
Common Name:	Radionuclide Brachytherapy Source
Class:	II
Classification:	21 CFR 892.5730 Product Code: 90-IWI

Predicate Devices Legally marketed devices to which equivalence is claimed.

1.

Trade Name:	OncoSeed™ (Iodine-125 seeds)
Common Name:	Radionuclide Brachytherapy Source
Class:	II
Classification:	21 CFR 892.5730 Product Code: 90-KXK
Cleared 510(k) No.:	K914281, FDA Cleared on November 22, 1991
Submitted by:	Medi-Physics Inc, dba GE Healthcare

Description of Device

The Brachytherapy Source Device, Model 9011, is a welded titanium capsule containing Iodine-125 adsorbed onto a silver rod.

Intended Use

The Brachytherapy Source Device, with apparent activities between 0.19mCi and 1.01mCi, is indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intra-abdominal, and intra thoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

The Brachytherapy Source Device, with total apparent activities greater than 1.01mCi, is indicated for interstitial treatment of tumors which have the following characteristics; unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants.

The Brachytherapy Source Device is indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with seeds.

When comparing the Intended Use and Indications for Use of the predicate OncoSeed, Model 6711, device, the Intended Use and Indications for Use of the subject device, Brachytherapy Source Device, Model 9011, has not changed.

Technological Characteristics

The following modifications have been incorporated in the subject device – Brachytherapy Source Device, Model 9011, when compared to predicate device, OncoSeed, Model 6711:

Modified Characteristics	**Brachytherapy Source Device Model 9011** (Subject Device)	**OncoSeed, Model 6711** (Predicate Device)
Seeds		
Regulatory Status	Subject Application	K914281
Capsule Material	Titanium, type A-40	Titanium, type A-40
Capsule Length	4.20 - 4.90mm (0.165 – 0.193in)	4.20 – 4.90mm (0.165 – 0.193in
Capsule Wall Thickness	0.051 – 0.0635mm (0.002 - 0.0025in)	0.051 – 0.0635mm (0.002 - 0.0025in)
Capsule Diameter	0.48 – 0.67mm (0.019 - 0.026in)	0.77 – 0.96mm (0.031 - 0.38in)
Carrier Substrate	99.9% silver	99.9% silver
Carrier Length	2.74 – 2.85mm (0.108 - 0.112in)	2.74 – 2.85mm (0.108 - 0.112in)
Carrier Diameter	0.27 – 0.33mm (0.011 - 0.013in)	0.48 - 0.53mm (0.019 – 0.021in)
Isotope	Iodine I-125	Iodine I-125
Sterilization	Not sterile (User Sterilized)	Not sterile (User sterilized)

Changes have only been made to the diameter of the capsule and carrier substrate diameter. All other technological characteristics of the subject seed remain unchanged compared to the predicate OncoSeed, Model 6711, 510(k) #K914281.

Nonclinical Test Data

The Brachytherapy Source Device, Model 9011, has been tested according to ISO 2919 for sealed sources, (test report section E) and activity measurements have been obtained from NIST Report (Report of Air-Kerma rate measurements) (see section F). In addition, Prototype sources have been manufactured and assessed against predetermined criteria for Design Verification and Design Validation (Declaration of Conformity Attachment 1).

Conclusion:

Upon reviewing the safety and effectiveness information provided in this submission and comparing the intended use, indications for use, method of use, the non-clinical test data and other technological characteristics, it can be concluded that the subject seed is substantially equivalent to the predicate OncoSeed, Model 6711, cleared under 510(k) # K914281.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Mr. David Risley
Director, US Regulatory Co-ordination Group
Medi-Physics, Inc. dba GE Healthcare
101 Carnegie Center
PRINCETON NJ 08540

Re: K081066
Trade/Device Name: Brachytherapy Source Device, Model 9011
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: IWG and KXK
Dated: April 14, 2008
Received: April 17, 2008

Dear Mr. Risley:

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 such 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

EXHIBIT-2

Indications for Use Form

510(k) Number (if known): K081066

Device Name: Brachytherapy Source Device, Model 9011

Indications For Use:

The Brachytherapy Source Device, with apparent activities between 0.19mCi and 1.01mCi, is indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intra-abdominal, and intra-thoracic tumors. Tumors of the head, neck, lung, pancreas and prostate (early stages) are commonly treated.

The Brachytherapy Source Device, with total apparent activities greater than 1.01mCi, is indicated for interstitial treatment of tumors which have the following characteristics; unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants.

The Brachytherapy Source Device is indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with seeds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081066

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)