
**CDRH - Premarket Notification (PMN or 510(k)) for 1998
December 1998 Listings
INTERSOURCE**

INTERSOURCE

Decision Date: December 10, 1998 **Received:** September 4, 1997

Applicant	INTERNATIONAL BRACHYTHERAPY, SA ZONE INDUSTRIELLE C SENEFFE BE 7180
Contact	VINCENT E CONIGLIONE
510(k) Number	K973328 Summary in PDF
Regulation Number	892.5730
Decision	Substantially Equivalent (SE)
Statement/Summary	Summary/Purged 510(k)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Product Code	SOURCE, BRACHYTHERAPY, RADIONUCLIDE (KXK)
Type	TRADITIONAL
Third Party Review	No
Expedited Review	No

IBt SA

Date: September 2, 1997

Page 18 of 21

Title: **Premarket Notification - InterSeed™**

K973328

7 510(K) SUMMARY**7.1 General Information**

Applicant / Manufacturing Site: IBt SA
 Zone Industrielle C
 7180 Seneffe - Belgium
 Tel: (+32) 64 / 520 800
 FAX: (+32) 64 / 555 397

Contact Person: Vincent E. Coniglione

Classification Name: Radionuclide Brachytherapy Source

Common/Usual Name: Palladium 103 Seed

Proprietary Name: InterSeed™

Establishment Registration Number: Registration application sent to FDA September 1997

Classification: Class II, same as the predicate device (see the Substantial Equivalence section below for predicate device information)

Special Controls: InterSeed™ will comply with the regulatory requirements for the Georgia Department of Natural Resources, Environmental Protection Division, Radioactive Materials Division for sealed sources.

Substantial Equivalence: InterSeed™ is substantially equivalent to Modified Palladium Seed Model 100 (Premarket Notification #K874787), a Class II post-amendment device granted clearance to market November 23, 1987.

7.2 The contents of this premarket notification summary will demonstrate the substantial equivalence of the subject device, InterSeed™, to the predicate device, Modified Palladium Seed Model 100. The substantial equivalence will be based on the following important features of the device:

- 7.2.1 Indications
- 7.2.2 Physical Size
- 7.2.3 Radiopaque Marker
- 7.2.4 Biocompatibility
- 7.2.5 Radioisotope
- 7.2.6 Radiation Dose

7.3 InterSeed™ Description

InterSeed™ is an hermetically sealed radiotherapeutic source indicated for interstitial implantation. The radionuclide used in InterSeed™ is Palladium 103 (Pd-103). InterSeed™ is constructed by placing a platinum radiopaque marker and Pd-103 on the surface of a medical grade titanium inner tube. The device is sealed by sliding an outer tube, also medical grade titanium, over the inner tube and laser welding both ends. The resulting device has a hollow center with an inner diameter of 0.35 mm with all body tissue contacting surfaces made from medical grade titanium.

Title: Premarket Notification - InterSeed™

7.4 Table 8 compares the indications statement drafted for InterSeed™ with the predicate device's indications statement.

Table 8: Indications Statement Comparison Summary

InterSeed™	Predicate Device
InterSeed™ implants are indicated for interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor. InterSeed™ implants are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy.	(Found on page 20 of K874787) Palladium Seeds are indicated for tumors with the following characteristics: localized, unresectable, low to moderate radiosensitivity. The tumors may be of the following type: superficial, intrathoracic, intraabdominal, lung, pancreas, prostate (stage A or B), residual following external radiation, and recurrent.

7.5 Based on the intent of the indications statement for the subject device, InterSeed™ is substantially equivalent to the predicate device with respect to its indications.

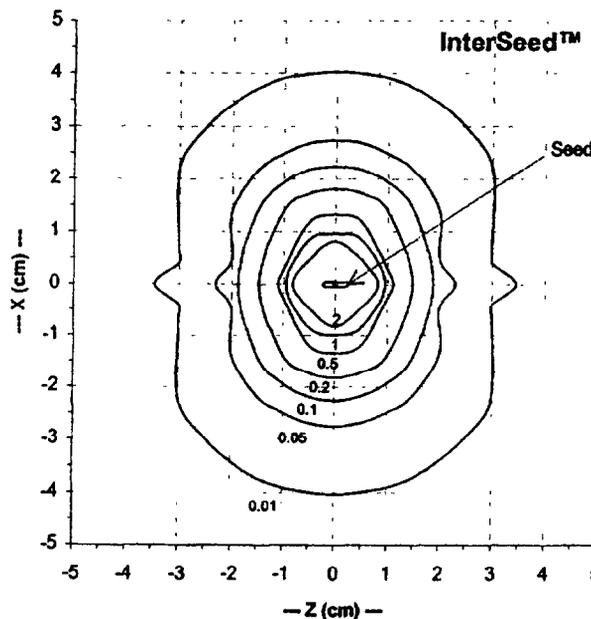
7.6 Table 9 compares the physical size, radiopaque marker, materials of construction, and the radioisotope for the subject device and the predicate device.

Table 9: Feature Comparison

Feature Description	InterSeed™	Predicate Device
Outer Tube	Medical grade titanium	Titanium
Length	4.5 mm	4.5 mm
Outside Diameter	0.81 mm	0.81 mm
Radiopaque Marker	Platinum	Lead
Isotope Carrier	Medical grade titanium	Aluminum cylinders
End Cup	Not Applicable	Titanium
Inner Tube	Medical grade titanium	Not Applicable
Seal Method	Laser Weld	Laser weld
Radioisotope	Palladium 103	Palladium 103
Half-life	17 days	17 days
Principal Energy Levels	20.1 keV, 20.2 keV 22.7 keV, 23.2 keV	20.1 keV, 20.2 keV 22.7 keV, 23.2 keV
Distribution of Isotope Binder	Deposited onto the surface of the isotope carrier	Distributed throughout the isotope carrier
Apparent Activity Levels	0.5 to 5.0 mCi	0.5 to 5.0 mCi
Residual Activity	< 0.1 µCi at 2 years	< 0.1 µCi at 2 years

Title: **Premarket Notification - InterSeed™**

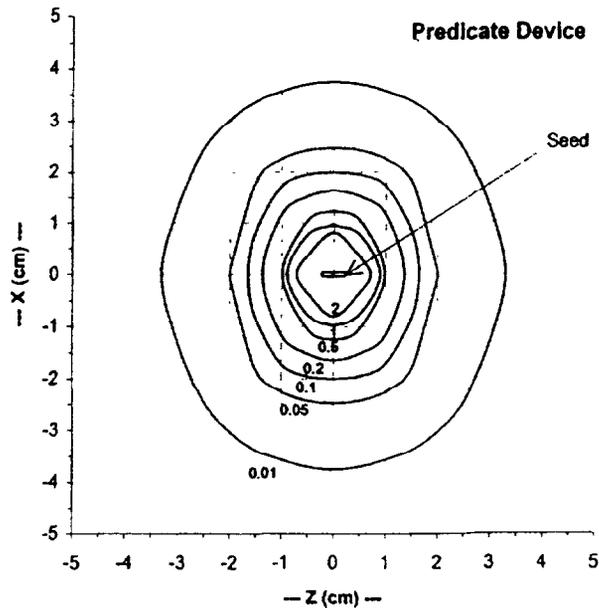
- 7.7 Based on the outside dimensions of the subject device being the same as the predicate device, both devices having a radiopaque marker, the body tissue contacting materials being made of a known biocompatible material, titanium, and both devices using Palladium 103 as the radionuclide, the subject device, InterSeed™ is substantially equivalent to the predicate device with respect to the physical size, presence of a radiopaque marker, biocompatibility, and radioisotope used.
- 7.8 The radiation dose of InterSeed™ and the therapeutic effect of the ionizing radiation emitted are characteristics of the radionuclide selected, Palladium 103, and the shape and placement of the internal components. Figure 7 is a graphical presentation of the computed values for the radiation dose delivered by InterSeed™ as a function of distance (both radial and axial). The graph depicts an isodose line represented by a smooth curve drawn through the data points that were linearly interpolated from the dose matrix data presented at 0.5 cm intervals. Figure 7 is to be compared with Figure 8 which represents comparable data from direct measurements for the predicate device which has been previously published.¹⁶



Isodose distribution produced by InterSeed™ source with an apparent activity of 1 mCi.

Figure 7: InterSeed™ Distribution of Radiation Dose

¹⁶ Meigooni, Ph.D., A.S., et al, "Dosimetry of Palladium 103 Brachytherapy Sources for Permanent Implants." *Endocurietherapy / Hypothermia Oncology*, Vol. 6, pp. 107-117, April 1990.



Isodose distribution produced by Pd-103 Model 200 source with an apparent activity of 1 mCi.

Figure 8: Predicate Device Distribution of Radiation Dose

- 7.9 The ratio of the average radiation emitted by the seed in all directions to the dose delivered at 90 degrees is a measure of the deviation of the angular distribution around the seed from that of an isotropic point source. The ratios for the subject device at distances of 1, 2, and 3 cm from the seed are 0.88, 0.85, and 0.85 respectively. The ratios for the predicate device at the same distances are 0.88, 0.86 and 0.86 respectively.
- 7.10 Based on InterSeed™ and the predicate device having a similar distribution of radiation dose and using the same radioisotope, InterSeed™ is substantially equivalent to the predicate device with respect to radiation dose.
- 7.11 Substantial Equivalence Summary
- 7.11.1 Based on the similar characteristics for indications, physical size, radiopaque marker, biocompatibility, radioisotope, and radiation dose between the subject device, InterSeed™, and the predicate device, InterSeed™ is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 10 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ruth Feicht
President
International Brachytherapy, Inc.
6000 Live Oak Parkway
Suite 107
Nocross, Georgia 30093

Re: K973328
InterSource (Palladium 103 Seed)
Dated: October 8, 1998
Received: October 9, 1998
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXX

Dear Ms. Feicht:

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 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/ocdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

