JUL 3 1 1998

K982421

510(k) Summary
International Isotopes , Inc.
Imagyn ^{125}I Seed

I. General Information on Submitter:

Name:	International Isotopes, Inc.
Address:	3100 Jim Christal Road
	Denton, TX 76207
Phone:	(940) 484-9492
Fax:	(940) 484-0877

Name of Contact Person:	Betsy C. King
	International Isotopes, Inc.
Phone:	(940) 484-9492
Fax:	(940) 484-0877

Date Summary Prepared: July 10, 1998

II. General Information on Device

Product Name: Imagyn ^{125}I Seed

Classification Name:

Source, Radionuclide, Brachytherapy, 21 C.F.R. § 892.5730

III. Predicate Devices:

EndoSeed, 510(k) number K914825/A

Amersham Model 6711, K914281

Mentor IoGOLD, K972271

IV. Description of the Device:

The Imagyn ^{125}I Seeds use ^{125}I beads encapsulated in a titanium tube.

V. Intended Use:

The Imagyn ^{125}I seeds with activities from 0.1 to 1.0 mCi are indicated for permanent interstitial implantation of selected localized tumors. They are to be used either as primary treatment (such as prostate cancer or unresectable tumors) or as treatment of residual disease after excision of the primary tumor or recurring tumors. Tumors of the head, neck, lung, pancreas, prostate (early stages), and other accessible tumors are commonly treated.

VI. Technological Characteristics of Device Compared to Predicate Device:

The Imagyn ^{125}I Seed uses the same type of encapsulation of ^{125}I as predicate devices. The range of activity is similar to other devices. There are no biocompatibility or other safety and effectiveness differences between this device and other predicate devices.

VII. Substantial Equivalence

The Imagyn ^{125}I Seed has been tested for safety and biocompatibility by standard tests used for radionuclide devices and found to safe and effective and substantially equivalent to other predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Betsy C. King
Director of Quality and
Regulatory Affairs
International Isotopes, Inc.
3100 Jim Christal Road
Denton, Texas 76207

Re: K982421
Imagyn ^{125}I Seed
Dated: July 10, 1998
Received: July 13, 1998
Regulatory class: II
21 CFR 892.5730/Procode: 90 IWG

Dear Ms. King:

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/cdrh/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

INDICATION FOR USE FORM

510 (k) Number (if known): K982421

Device Name: Imagyn ^{125}I Seed

Indications for Use:

Imagyn^{125}I Seeds with activities from 0.1 to 1.0 mCi are indicated for permanent interstitial implantation in selected localized tumors. They can to be used either as primary treatment (such as prostate cancer or unresectable tumors) or treatment for residual disease after excision of the primary tumor or recurring tumors. Tumors of the head, neck, lung, pancreas, prostate (early stages), and other accessible tumors are commonly treated.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982421

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.1091

(Optional Format 1-2-96)