

SUMMARY OF SAFETY AND EFFECTIVENESS

K990193

General Company Information

Name: Implant Sciences Corporation
Address: 107 Audubon Road, #5
Wakefield, MA 01880-1246
Telephone: (781) 246 – 0700
Fax: (781) 246 – 1167

General Device Information

Product Name: Implant Sciences "I-plant" ¹²⁵Iodine Brachytherapy Seeds (Model 3000)
Classification: Brachytherapy Radionuclide Source, 21 CFR 892.5730 - Class II

Predicate Devices

North American Scientific, Inc. (NASI) IoGold™ I-125 Brachytherapy Source (Model MED3631-A) [510(k) K972271]

Medi-Physics, Inc. (Amersham) I-125 Seeds (No. 6711) [510(k) K914281]

International Isotopes, Inc. Imagyn ¹²⁵Iodine Brachytherapy Seed [510(k) K982421]

Theragenics Corp. (Nuclear Medicine, Inc.) TheraSeed® Palladium 103 Implants (Model 100) [510(k) K852542 and K874787]

Description

The Implant Sciences ¹²⁵Iodine Brachytherapy Seeds consist of a laser welded titanium capsule containing an aluminum clad copper rod that serves as both a substrate for the radioactive iodine source and as a radiopaque x-ray marker. The marker identifies the source location and orientation. The seeds are provided non-sterile and must be sterilized prior to use.

Intended Use

The Implant Sciences ¹²⁵Iodine Brachytherapy Seeds with activities from 0.1 to 5.0 mCi are indicated for temporary or permanent interstitial or intracavity implantation or surface application to treat selected localized tumors. They can be used either as primary treatment (such as for prostate cancer or unresectable tumors) or as treatment for residual

disease after excision of primary or recurrent tumors. The ¹²⁵Iodine Seeds may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate and other accessible tumors are commonly treated.

Technological Characteristics Versus Predicate Devices

The Implant Sciences ¹²⁵Iodine Brachytherapy Seeds use the same titanium capsule material and are the same physical dimensions (length and diameter) as the predicate devices. The range of apparent activity levels is similar to that of the predicate devices. The results of safety testing in accordance with the ANSI Standard for Sealed Radioactive Sources (ANSI/HPS N43.6 - 1997) are consistent with the test results for the predicate devices.

Substantial Equivalence

This 510(k) Notice supports the position that the Implant Sciences ¹²⁵Iodine Brachytherapy Seeds are substantially equivalent in design and function to the North American Scientific, Inc. (NASI) IoGold™ I-125 Brachytherapy Source (Model MED3631-A) [510(k) K972271], the Medi-Physics, Inc. (Amersham) I-125 Seeds (No. 6711) [510(k) K914281], the International Isotopes, Inc. Imagyn ¹²⁵Iodine Brachytherapy Seed [510(k) K982421] and the Theragenics Corp. TheraSeed® Palladium 103 Implants (Model 100) [510(k) K852542] which are brachytherapy radionuclides that have previously been cleared for marketing under the Premarket Notification regulations. Each of these devices has been placed in the same classification category (21 CFR 892.5730) as the ISC Brachytherapy Seeds; and each is appropriate for the same clinical application.

The 510(k) Notice contains summaries of both *in vitro* studies which were conducted to evaluate the safety, and appropriateness of the ISC Brachytherapy Seeds. Data are presented which demonstrate that the ISC Brachytherapy Seeds satisfy performance requirements for temperature resistance, external pressure resistance, impact resistance, vibration integrity, and puncture resistance as specified by ANSI Standard N43.6-1997. These test results confirm that the ISC ¹²⁵Iodine Brachytherapy Seeds meet the requirements for radioactive sources in its class and are equivalent to other currently marketed radionuclide brachytherapy sources. The 510(k) Notice also describes further standardized studies which describe the radiation profile of the sources. These profiles are consistent with the data generated from other Iodine-125 brachytherapy seeds with similar physical geometries. In addition, capsule leak testing was carried out in accordance with ANSI standards. The results of these studies again support the equivalence of the Implant Sciences device to the predicate devices.

Both the ISC device and the predicate devices are provided non-sterile and must be sterilized by autoclave or ethylene oxide at the hospital prior to use. The manufacturing and cleaning processes for the seeds introduce no new chemical or biological entities to the surface of the device.

Implant Sciences believes that the information provided establishes that similar legally marketed and pre-enactment devices have been used historically for the same types of clinical applications as the Implant Sciences ¹²⁵Iodine Brachytherapy Seeds. The materials from which the Implant Sciences device is fabricated have an established history of use in medical applications, and the specific materials used by Implant Sciences have been thoroughly tested in accordance with applicable guidelines.



MAY 20 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howard Schrayer
Implant Sciences Corporation
107 Audobon Road, No. 5
Wakefield, Massachusetts 01880-1246

Re: K990193
125 Iodine Brachytherapy Seeds (Model 3000)
Dated: April 13, 1999
Received: April 14, 1999
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Mr. Schrayer:

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) Number (if known): K990193

Device Name: Implant Sciences ¹²⁵Iodine Brachytherapy Seeds – (Model 3000)

Indications For Use:

The Implant Sciences ¹²⁵Iodine Brachytherapy Seeds with activities from 0.1 to 5.0 mCi are indicated for temporary or permanent interstitial or intracavity implantation or surface application to treat selected localized tumors. They can be used either as primary treatment (such as for prostate cancer or unresectable tumors) or as treatment for residual disease after excision of primary or recurrent tumors. The ¹²⁵Iodine Seeds may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate and other accessible tumors are commonly treated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K990193

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use