K994317
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MAR 21 2000

## SUMMARY OF SAFETY AND EFFECTIVENESS

### 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" $^{125}$ Iodine Brachytherapy Seeds (Model 3500)

Classification: Brachytherapy Radionuclide Source, 21 CFR 892.5730 - Class II

### Predicate Devices

Implant Sciences, Inc. I-Plant™ I-125 Brachytherapy Seeds (Model 3000) [510(k) K990193]

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

### Description

The Implant Sciences $^{125}$ Iodine (Model 3500) Brachytherapy Seeds consist of a laser welded titanium capsule containing a silica capillary tube that serves as a substrate for the radioactive iodine source. The tube is positioned around a silver radiopaque x-ray marker that identifies the source location and orientation. The seeds are provided non-sterile and must be sterilized prior to use.

### Intended Use

The Implant Sciences $^{125}$ Iodine (Model 3500) 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 $^{125}$ Iodine 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 $^{125}$ Iodine 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 $^{125}$ Iodine (Model 3500) Brachytherapy Seeds are substantially equivalent in design and function to the Implant Sciences (Model 3000) $^{125}$ Iodine Brachytherapy Seed [510(k) K990193] and the Medi-Physics, Inc. (Amersham) I-125 Seeds (No. 6711) [510(k) K914281], which are brachytherapy radionuclides that have previously been cleared for marketing under the Premarket Notification regulations. These devices have been placed in the same classification category (21 CFR 892.5730) as the ISC Model 3500 seeds; and each is indicated for the same clinical application.

The 510(k) Notice contains summaries of *in vitro* studies which were conducted to evaluate the safety, and appropriateness of the ISC Model 3500 Brachytherapy Seeds. Data are presented which demonstrate that the Model 3500 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 $^{125}$ Iodine (Model 3500) 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 also support the equivalence of the ISC Model 3500 device to the predicate devices.

Both the Model 3500 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 predicate devices have been used historically for the same types of clinical applications as the Implant Sciences $^{125}$ Iodine (Model 3500) 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2000

Howard L. Schrayer
Implant Sciences Corp.
107 Audubon Road #5
Wakefield, MA 01880-1246

Re: K994317
I-plant Model 3500 (125-Iodine Brachytherapy Seeds)
Dated: December 21, 1999
Received: December 22, 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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K994317

Device Name: Implant Sciences $^{125}$ Iodine Brachytherapy Seeds – (Model 3500)

Indications For Use:

The Implant Sciences $^{125}$ Iodine 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 $^{125}$ Iodine 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)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

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

David C. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994317

**(Optional Format 1-2-96)**