MAR 21 2000 K023242

SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 04 2002

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

DEC 0 4 2002

Mr. John J. Munro III
Vice President, Brachytherapy Products
Implant Sciences Corporation
107 Audubon Road, #5
WAKEFIELD MA 01880-1246

Re: K023242
Trade/Device Name: I-Plant Model 3500 (125 Iodine Brachytherapy Seeds)-Sterile
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: November 5, 2002
Received: November 6, 2002

Dear Mr. Munro:

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 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

510(k) Number: K023242

Device Name: Implant Sciences Corp. I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed)-Sterile

Indications for Use:

Implant Sciences I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed)-Sterile with individual activities from 0.1 to 5.0 mCi are indicated for temporary or permanent interstitial, intracavitary, intraluminal or intraoperative implantation or surface application to treat selected localized tumors. They can be used either as primary treatment, such as for prostate cancer or for unresectable tumors, or as treatment for residual disease after excision of primary or recurrent tumors. I-Plant Model 3500 Brachytherapy 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, breast 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023242