



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

IntraMedical Imaging, LLC
% Farhad Daghighian, Ph.D.
President
12569 Crenshaw Blvd.
HAWTHORNE CA 90250

November 21, 2014

Re: K142668
Trade/Device Name: Lesion-Loc I-125 Seed/Needle
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXX
Dated: September 30, 2014
Received: October 1, 2014

Dear Dr. Daghighian:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K142668

Device Name
Lesion-Loc I 125 Seed/Needle

Indications for Use (Describe)

Lesion-Loc I-125 Seed/Needle is indicated in the use for localization of lesions (as shown by mammogram or ultrasound) in the breast or other tissue under the direct supervision of a qualified physician. The device is indicated as "single-use sterile device". Lesion-Loc I-125 Seed/needle is not intended for permanent implantation and should be removed in a few days after implantation. It is to be used in conjunction with the Gammaprobe® (IntraMedical Imaging) for localization of lesions (as shown by a mammogram or ultrasound images) in the breast and other tissues.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Appendix A: 510(k) Summary of Safety and Effectiveness

Statement Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device Name: Lesion-Loc I-125 Seed/Needle

Device Model

Number: LL 125-XX (XX indicates length of needle – 05, 07, 10 & 15 cm)

Device

Classification

Name: Source, Brachytherapy, Radionuclide (KXX) 21 CFR 892.5730

Device

Classification: Class II (Radiology)

Predicate

Device: Best® Localization Needle with I-125 Source (K122704)

Manufacturer: IntraMedical Imaging
12569 Crenshaw Blvd.
Hawthorne, CA 90250

Establishment

Registration

Number: 2031874

Official Farhad Daghighian

Contact: President and Chief Scientist Farhad Daghighian, Ph.D.
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Intended Use: The Lesion-Loc I-125 Seed/Needle is intended for clinical use in the marking of lesions with the seed in close proximity to or within the lesion site. The lesion (as seen in a mammogram or ultrasound image) is then located using an appropriate hand held gamma radiation detector.

Device Description: Lesion-Loc I-125 Seed/Needle contains a source 4.5 mm long and 0.8 mm in diameter. The source consists of a welded titanium capsule with a 0.05 mm thick wall and a silver rod, which is about 4 mm length with the active material as silver iodide on the surface, welded inside the titanium capsule. The seed is contained in a needle. The needles used are standard 18 gauges available commercially in lengths up to 15 cm. The I-125 seed is loaded inside the needle. The radioactive seeds are introduced into the lesion area as directed by a radiologist per Written Directive and prescription. The devices are packaged in a pouch with label and provided sterile.

Technological characteristics The Lesion-Loc I-125 Seed/Needle uses the Theragenics Corporation AgX100 (having a 510k number K103319) seed that typically has less radioactive strength than those used for brachytherapy. I-125 has a half-life of about 60 days and decays by electron capture with the emission of characteristic photons and electrons. The titanium walls of the seed absorb the electrons but the photons continue through the walls. An appropriate hand held gamma radiation detector probe is used to locate the seed and therefore also the lesion (as seen in a mammogram or ultrasound image).

Performance data The Lesion-Loc I-125 Seed/Needle is based on Theragenics Corporation AgX100 seed (having a 510k number K103319) design and commercially available needle implant technology. Theragenics Corporation (Buford, GA, USA) contract manufactures the seed/needle device and provides the sterilized product to IntraMedical Imaging only after meeting all the performance qualification. A number of performance tests are done by Theragenics on the seed as per ISO 2919. IntraMedical Imaging distributes the Seed/Needle device for localization only as prescribed by a physician at a licensed hospital or other medical institution.

Conclusion The technological characteristics and intended use of the Lesion-Loc I-125 Seed/Needle is substantially equivalent as the predicate device: Best® Localization Needle with I-125 Source.

Please note that the predicate Best Medical is identical in shape and size and the indication for use is also localization. Further conclusion is that also the OEM Theragenics Corporation Model AgX100 has been certified as safe, biocompatible and has been in clinical use for radiation therapy use without complaints.