

4/16/99

K9 84446

Premarket Notification 510(k) Summary

Mills Biopharmaceuticals, Inc.
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Contact Person: Stanley L. Mills, Ph.D.
Date of Summary Preparation: 10 December 1998

Device Classification

Name: SOURCE, BRACHYTHERAPY, RADIONUCLIDE
Trade Name: MBI I-125 Brachytherapy Seed
Common Name: I-125 Brachytherapy Seed
Equivalence: Model 6711 by Amersham/Medi-Physics, Inc.(K914281)
Description: Each MBI I-125 Brachytherapy Seed external dimensions of 4.55 mm \pm 0.35 mm in length and 0.865 mm \pm 0.095 mm in diameter. The cylindrical metal casing is titanium having a wall thickness of 0.06 mm \pm 0.02 mm laser welded at both ends. Both models: 125SL and 125SH have three to five silver spheres which are used to absorb iodine-125 and provide X-ray contrast.
Intended use: MBI I-125 Brachytherapy Seeds with apparent activities between 3.7 MBq (0.1 mCi) to 37 MBq (1.0 mCi) are indicated for permanent interstitial treatment of tumors which are unresectable or residual after excision of the primary lesion, localized, slow growing, and exhibit low to moderate radiosensitivity. Intra abdominal, intrathoracic and superficial tumors may be treated with seeds containing apparent activities within this range. Tumors commonly treated are prostate (early stage), pancreas, head, neck, and lung.

MBI I-125 Brachytherapy Seeds containing apparent activities greater than 37 MBq (1.0 mCi) are indicated for temporary interstitial treatment of tumors which are unresectable or residual after excision of the primary lesion, localized, and exhibit moderate radiosensitivity. Temporary implants are indicated in breast, brain and eye tumors.

MBI I-125 Brachytherapy Seeds are indicated for treatment of residual tumors and recurrent tumors following external radiation therapy, hyperthermia, or chemotherapy or concurrent use with these treatment modalities.

Technological Characteristics:

Model 6711, Model 125SL, and 125SH all encapsulate with titanium and seal by welding the ends closed. Model 6711, I-125 Seeds differ from our design in the composition of the interior absorbing material. Model 6711, I-125 Seeds the I-125 is adsorbs onto a single silver rod which also provides for radiographic visualization. In the Model 125SL and 125SH the I-125 is adsorbed onto silver spheres which also provide radiographic visualization.

NonClinical Data:

Photon emission spectra was determined using an intrinsic Ge detector. The spectrum was obtained transverse to the seed axis and consisted of three photon peaks of energy 27.4, 31.4, and 35.5 keV. In addition, two additional peaks at 22.1 and 25.5 keV were identified as fluorescent x-rays from the silver spheres.

Total radiation fluence distribution data as determined by an intrinsic Ge detector analyzed with a multichannel analyzer. The I-125 seeds were mounted on a thin plastic rod capable of being precisely rotated about 360° in 5° increments. The mounting rod was designed to be adjusted to place the seed in the center of the detector and at a distance of one meter. Five I-125 seeds were analyzed along both the short and long axis. The data was averaged and plotted in the polar coordinate system where the radial distance represents the relative magnitude of photon fluence in various directions with respect to the seed axis.

Conclusion:

The photon emission spectra and total radiation fluence distribution data is consistent between Amersham/Medi-Physics, Inc. Model 6711 and Mills Biopharmaceuticals, Inc. Model 125SL. The emission spectra consisted of five energy peaks at 22.1, 25.5, 27.4, 31.4, 35.5 keV. Total radiation fluence distribution is similar between the two different models when compared to published data for the Model 6711 (Ling, C.C., Yorke, E.D., Spiro, I.J., Kubiatowicz, D., Bennett, D.: Physical dosimetry of ¹²⁵I seeds of a new design for interstitial implant. *Int. J. Radiation Oncology Biol. Phys.*, 9:1747-52, 1983).



APR 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Stanley L. Mills, Ph.D.
Mills Biopharmaceuticals Incorporated
120 N.E. 26th Street
Oklahoma City, OK 73105Re: K984446
MBI I-125 Brachytherapy Seed Models 125SL
and 125SH
Dated: March 26, 1998
Received: March 29, 1998
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXX

Dear Dr. Mills:

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

