

Summary of Safety and Effectiveness Information

Summary of Safety and Effectiveness Information

Submitter and Owner

Company name Eckert & Ziegler BEBIG GmbH
Establishment Registration number 9617477
Address Robert Rössle Str. 10
13125 Berlin, Germany
Correspondent Sven Langer
Regulatory Affairs
Phone: +49 30 941084-734
Fax: +49 30 941084-770
Summary prepared: May 6, 2014

Device Name

Trade / Proprietary name IsoSeed I25.S17plus
Common / Usual name brachytherapy Iodine-125 source
Classification Class II
Regulation, Panel, Productcode 21 CFR 892.5730 Radionuclide brachytherapy source
Radiology, Product code KXX

Predicate Devices

Device	Premarket #
Nucletron SelectSeed I-125	K002429
Eckert & Ziegler BEBIG IsoSeed I-125	K033781
Medi-Physics OncoSeed 6711	K914281

Device Description

IsoSeed I25.S17plus is a radioactive brachytherapy source intended for permanent as well as temporary implantation. IsoSeed I25.S17plus is a cylindrical sealed source containing radioactive Iodine-125. The source is 4.5 mm long and 0.8 mm in diameter. The outer capsule of the source is composed of titanium according to ASTM F67. The radioactive iodine I-125 is deposited as silver iodide (AgI) on the surface of a silver bar. The silver bar also serves as an X-ray marker.

Iodine-125 has a half-life of 59.41 days. It decays with 100% to Te-125 as a result of electron capture by the radiation of X-rays and γ -radiation in the energy range up to 35 keV. The most commonly used activities used for implants are up to 1.045 mCi. Other source strengths for temporary applications are available up to 25 mCi.

IsoSeed I25.S17plus is delivered non-sterile and must be steam sterilized by the user. The device is intended for single use, unless it is used as temporary implant without direct tissue contact.

Intended Use

Indications for Use

IsoSeed I25.S17plus with apparent activities from 0.189 to 1.045 mCi are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intraabdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

IsoSeed I25.S17plus with total apparent activities greater than 1.045 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants. IsoSeed I25.S17plus are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with IsoSeed I25.S17plus.

The indications statement of IsoSeed I25.S17plus is the same as for the predicate device OncoSeed 6711. Only the activity range for implants in the indications for use differs slightly due to the specification of homogenous activity classes used by Eckert & Ziegler BEBIG GmbH. This difference is therapeutically irrelevant.

Summary and comparison of technological characteristics

IsoSeed I25.S17plus has the same design as the selectSeed. Like the predicate device it is a cylindrical sealed source which is 4.5 mm long and 0.8 mm in diameter. The outer capsule of the source is composed of titanium according to ASTM F67. Radioactive iodine I-125 is deposited as silver iodide (AgI) on the surface of a silver bar contained in the capsule.

The indications of IsoSeed I25.S17plus are the same as for OncoSeed 6711. The activity range from 0.2 to 25 mCi is similar to the standard activity range of OncoSeed 6711 which is 0.2 to 21 mCi (up to 40 mCi available by special request) and is appropriate for the intended use of IsoSeed I25.S17plus. IsoSeed I25.S17plus is packaged non-sterile in a radiation protection capsule. The packaging is similar to IsoSeed I-125.

Summary of Nonclinical Testing

Tests according to ISO 2919 have been carried out. IsoSeed I25.S17plus has been classified under C 63X11. Furthermore IsoSeed I25.S17plus has passed tests for MR compatibility according to ASTM F2503, ASTM 2052, ASTM 2213, ASTM 2182, and ASTM 2119. Biocompatibility has been confirmed according to ISO 10993-1 and has been tested according to ISO 10993-5 and ISO 10993-18. These nonclinical tests have been performed to support safety claims. They are not relied on for a determination of substantial equivalence with the predicate devices.

K140849
Page 3 of 3

Summary of Safety and Effectiveness Information



Summary of Clinical Testing

Not applicable

Conclusion of Substantial Equivalence

IsoSeed I25.S17plus has the same design as the selectSeed. The indications of IsoSeed I25.S17plus are the same as for OncoSeed 6711. The packaging is similar to IsoSeed I-125. Upon reviewing the safety and effectiveness information provided in this submission and comparing the intended use, indications for use, and their technological characteristics it can be concluded that IsoSeed I25.S17plus is substantially equivalent to its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Eckert & Ziegler BEBIG GmbH
% Mr. Sven Langer
Regulatory Affairs
Robert Rossle Str.10, 13125 Berlin
GERMANY

July 2, 2014

Re: K140849
Trade/Device Name: IsoSeed (Model 125.S17plus)
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXX
Dated: March 31, 2014
Received: April 3, 2014

Dear Mr. Langer:

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.

Page 2—Mr. Langer

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,



for

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

Enclosure

19165

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K140849

Device Name

IsoSeed 125.S17plus

Indications for Use (Describe)

IsoSeed 125.S17plus with apparent activities from 0.189 to 1.045 mCi are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intraabdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

IsoSeed 125.S17plus with total apparent activities greater than 1.045 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants. IsoSeed 125.S17plus are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with IsoSeed 125.S17plus.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 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)

Michael D. O'Hara