

K993552

MAR 31 2000

510(k) Summary of Safety and Effectiveness

BEBIG IsoSeeds® Pd-103

**Company Name**

BEBIG Isotopentechnik und Umweltdiagnostik GmbH  
Robert Rössle Str. 10  
13125 Berlin, Germany

**Official Contact**

Sven Langer  
Regulatory Affairs

**Device Name**

Proprietary Name: BEBIG IsoSeeds® Pd-103  
Common Name: Brachytherapy Palladium-103 Sources  
Classification Name: 21 CFR 892.5730 Radionuclide Brachytherapy Source

**Predicate Devices used for Substantial Equivalence**

Device	Premarket #
UroMed Brachytherapy Iodine-103 Source	K982226
Theragenics Modified Palladium Seed	K874787

**Intended Use**

The BEBIG IsoSeeds® Pd-103 are intended for use in the treatment of cancer with radioactive sources in close proximity to or within the tumor.

**Indications for use**

The BEBIG Pd-103 Radionuclide Brachtherapy Sources are indicated for the treatment of selected localized tumors. These sources are commonly used to treat superficial, intra-abdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas and prostate are commonly treated. They may be used alone, or in combination with external beam radiation.

**Description**

The BEBIG IsoSeeds® Pd-103 are cylindrical sealed sources containing Pd-103 radioactivity. The sources are 4.5 mm long and 0.8 mm in diameter. The outer capsule of the source is composed of titanium being closed at one end and sealed by a laser weld at the other end in a final step. The metallic palladium-103 is deposited within a porous ceramic tube. A radiopaque marker is located in the center of the ceramic tube to serve as an x-ray marker. The radiopaque marker is composed of gold wire.

Palladium seeds have a half live of 16,97 days and are available in a range of activity levels. The BEBIG IsoSeeds® Pd-103 are provided non-sterile and must be sterilized prior to use.

## **Summary of Standards Achieved**

Medizinproduktegesetz (German Law concerning medical devices)

Directive 90/385/EEC for active implants

DIN EN 1441 Medical devices- Risk analysis

DIN EN 25426 Sealed radioactive sources - Classification, requirements, test methods

ISO 2919 sealed radioactive sources - General requirements and classifications

ISO 9978: 1992(E), Radiation Protection-Sealed radioactive sources- Leakage test Methods

ANSI/HPS N43.6-1997-Sealed Radioactive Sources Classification

ASTM Standard for Titanium: F67-95 rev. 95 grade 2

DIN EN 554 Sterilization of medical devices - Validation and routine control of steam sterilization

DIN EN 980 Graphic Symbols used for labeling of medical devices

DIN EN 1041 Terminology, symbols and information associated with medical devices

DIN EN 25430 Radiation safety labeling

ISO 90001: Quality Management Systems

ISO 46001: Medical devices quality system

FDA Quality System Regulation 21 CFR Part 820 Good Manufacturing Practice.

DIN EN 6804 Radiation safety regulations for handling sealed radiation sources

DIN EN 25407 Shielding from ionizing radiation

DIN EN 25422 Storing of radioactive devices - Protection from radiation fire and theft

DIN EN 25425 Radionuclide labs - Design, radiation safety and fire protection

## **Summary**

In Summary, the BEBIG IsoSeeds® Pd-103 are substantially equivalent to legally marketed devices. Quality System Controls assure the device is substantially equivalent to predicate devices with respect to its performance, safety, and effectiveness.

## **10. Certificates**

- TÜV Certificate for quality system according to 46001
- Certificate of ISO-Classification with protocol



MAR 31 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sven Langer  
Regulatory Affairs  
BEBIG Isotopentechnik und Umweltdiagnostik GMBH  
Robert-Rossle/Str.10  
D-13125 Berlin-Buch,  
Germany

Re: K993552  
IsoSeed Pd-103  
Dated: January 10, 2000  
Received: January 19, 2000  
Regulatory class: II  
21 CFR 892.5730/Procode: 90 KXX

Dear Mr. Langer:

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)

1 of 1

**510(k) Premarket Notification Indication for Use  
BEBIG Brachytherapy Palladium-103 Sources**

510(k) Number (if known): K 993552

Device Name: BEBIG IsoSeed® Pd-103

**Indications for Use:**

The BEBIG Pd-103 Radionuclide Brachtherapy Sources are indicated for the treatment of selected localized tumors. These sources are commonly used to treat superficial, intra-abdominal and intrathoracic tumors. Tumors of the head, neck, lung, pancreas and prostate are commonly treated. They may be used alone, or in combination with external beam radiation.

David A. Johnson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K993552

Prescription Use ✓  
(Per 21 CFR 801.109)