K093663

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

DEC 23 2009

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc. Bard Medical Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	Julie Bassett
Contact Person's Telephone Number:	770-784-6375
Contact Person's Fax:	770-385-4706

B. DEVICE NAME:

Device Name:	Brachytherapy seed implants
Trade Name(s):	BrachySource® Brachytherapy Seed Implants
Common/Usual Name:	Brachytherapy seed implants
Classification Names:	90KXK – Source, Brachytherapy, Radionuclide
CFR Reference:	21 CFR 892.5730 – Radionuclide Brachytherapy Source, Class II

C. PREDICATE DEVICE NAME:

Trade Names:	BrachySource® Brachytherapy Seed Implants K043246

D. DEVICE DESCRIPTION:

BrachySource® Seed Implants consist of a welded titanium capsule containing Iodine-125 absorbed onto a nickel/copper coated, gold cored aluminum wire. The implants are nominally 4.5mm long by 0.8mm in diameter.

Iodine-125 has a half-life of 59.6 days and decays by electron capture with the emission of characteristic photons and Auger electrons. The principal photon emissions are 27.4 and 31 keV x-rays and a 35.5 keV gamma. The titanium wall of the BrachySource Seed Implant absorbs the electrons.

E. INTENDED USE:

BrachySource® Seed Implants are indicated for permanent interstitial treatment of selected localized tumors such as: head and neck, lung, pancreas, and early stage prostate. BrachySource® Seed Implants may be used in superficial, intra-abdominal, and intra-thoracic locations. BrachySource® Seed Implants are indicated to treat residual tumors following completion of a course of external radiation therapy and for recurrent tumors.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject BrachySource® Brachytherapy Seed Implants have the same intended use, general design and fundamental scientific technology as the predicate device.

G. PERFORMANCE DATA SUMMARY:

The appropriate bench testing to determine substantial equivalence was completed.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

DEC 23 2009

Ms. Julie Bassett
Regulatory Affairs Specialist
C. R. Bard, Inc.
Bard Medical Division
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K093663
Trade/Device Name: BrachySource® Brachytherapy Seed Implants
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: November 23, 2009
Received: November 25, 2009

Dear Ms. Bassett:

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.4 Indications for Use Statement

510(k) Number (if known): K093663

Device Name: BrachySource® Brachytherapy Seed Implants

Indications for Use:

BrachySource® Seed Implants are indicated for permanent interstitial treatment of selected localized tumors such as: head and neck, lung, pancreas, and early stage prostate. BrachySource® Seed Implants may be used in superficial, intra-abdominal and intra-thoracic locations. BrachySource® Seed Implants are indicated to treat residual tumors following completion of a course of external radiation therapy and for recurrent tumors.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093663