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

FEB - 2 2005

K043246

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 Urological Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John C. Knorpp
Contact Person's Telephone Number:	770-784-6451
Contact Person's Fax:	770-784-6419
Date of Preparation:	November 22, 2004

B. DEVICE NAME:

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

C. PREDICATE DEVICE NAME:

Trade Name(s): I-125 Implant Seed, STM 1251

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® Seed Implants have the same intended use, design and fundamental scientific technology as the predicate device.

G. **PERFORMANCE DATA SUMMARY:**

The appropriate testing for the modification of the BrachySource® Seed Implant was conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2005

Mr. John C. Knorpp
Sr. Regulatory Affairs Specialist
Bard Urological Division
C. R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K043246
Trade/Device Name: BrachySource® Brachytherapy Seed Implant
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: November 22, 2004
Received: November 23, 2004

Dear Mr. Knorpp:

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 (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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K043246

Device Name: BrachySource® Brachytherapy Seed Implant

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)

David R. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043246

(Recommended Format 11/13/2003)