K140856
Page 1 of 2

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

MAY 02 2014

BARD | MEDICAL

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps 510(k) premarket notification.

Sponsor:
BARD Medical Division
C.R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014
Establishment Registration Number: 1018233

Contact:
Michele Davis, RAC
Regulatory Affairs Project Manager
Bard Medical Division
Tel: 770-784-6274
Fax: 770-385-4706

Date:
April 2, 2014

Subject Device:
Trade Name: BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps
Common or Classification Name: Radionuclide Brachytherapy Source
Regulation: 21 CFR 892.5730
Classification: II
Product Code: KXK

Legally marketed device to which substantial equivalence is claimed:

- BrachySource® Brachytherapy Seed Implants, K093663

Device Description

BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps consist of a seed implant with bioabsorbable caps fitted onto each end of the seed. The seed implant is a welded titanium capsule containing Iodine-125 adsorbed onto a nickel/copper coated, gold cored aluminum wire. The bioabsorbable caps are composed of 70% L-lactide and 30% D,L-lactide copolymer.

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 35.5 keV gamma. The titanium wall of the BrachySource Seed Implants absorbs the electrons. The bioabsorbable caps break down over 18-24 months and do not impact the emissions from the Iodine-125 seed.

Intended Use

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

Technological Characteristics

BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps has the same intended use and fundamental scientific technology as the predicate device, BrachySource® Brachytherapy Seed Implants. The difference between the subject and predicate device is the addition of bioabsorbable caps on the ends of the seed to increase the surface area of the seed and aid to resist movement of the seed within the tissue. The modification to the BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps is deemed equivalent to the current device, BrachySource® Brachytherapy Seed Implants (K093663).

Performance Data

The modified device, BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps, have been tested via nonclinical functional performance testing. Nonclinical functional performance tests included testing to verify the assembly and integrity of the bioabsorbable caps with the seed and the interface of the seed with bioabsorbable caps within brachytherapy implant needles.

The bioabsorbable caps are the same material as the SourceLink® Brachytherapy Seeding Spacer Links (K041576). The SourceCap Bioabsorbable Caps and SourceLink® Links have the same patient contact and duration. The requirements per ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA Bluebook Memorandum G95-1, Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation of Testing" have been met for this material.

Substantial Equivalence

The BrachySource Seed Implants with SourceCap Bioabsorbable Caps has the same indications for use and fundamental scientific technological characteristics as the predicate device. Based on this, the design and the summary of design control activities provided in this submission, the proposed BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps has been shown to be substantially equivalent to the cleared BrachySource® Brachytherapy Seed Implants, K093663.

Conclusion:

The modified device, BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps, is substantially equivalent to the predicate device, BrachySource® Brachytherapy Seed Implants.

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

May 2, 2014

C. R Bard, Inc.
% Ms. Michele Davis
Regulatory Affairs Project Manager
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K140856
Trade/Device Name: BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: April 2, 2014
Received: April 3, 2014

Dear Ms. Davis:

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.

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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140856

Device Name

BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps

Indications for Use *(Describe)*

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

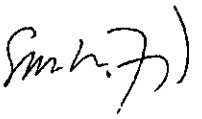
Type of Use *(Select one or both, as applicable)*

☒ 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)*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."