AUG 0 2 2002

K020150

CAPINTEC, INC.

January 10, 2001

RE: Summary of Safety and Effectiveness Information for the Capintec CRC 15BT calibrator.

The CRC 15BT dose calibrator is a well type ionization chamber specifically designed to accurately and rapidly measure all types of brachytherapy sources with appropriate calibration and source positioning device. The ionization chamber is connected to a readout, which converts measured current into a displayed value in units of either Ci (activity) or U (air kerma strength). The unit is sealed and pressurized with UPC Argon, which improves sensitivity and eliminates the need for temperature and pressure corrections.

The CRC 15BT has been evaluated by the University of Wisconsin ADCL, and found to be a suitable instrument for all clinically available gamma and high-energy beta brachytherapy sources, including HDR, LDR, and IVBT in any number of configurations including, seeds, ribbons, and source trains with appropriate source holders.

The CRC 15BT design is a minor modification to the Capintec CRC 15R dose calibrator to increase the activity range to accommodate HDR sources. The CRC 15R has been commercially available for over 10 years and has an excellent reputation for long term stability, reliability, safety and effectiveness. The modifications to the 15BT are limited to reduced fill gas pressure and in increase bias voltage to accommodate a higher activity range required for HDR sources. The basic chamber design and readout are the same as the CRC 15R. Consequently, the CRC 15BT is expected to maintain the same excellent quality as the CRC 15R, with the same level of safety and effectiveness and long term reliability.

The CRC 15BT has also been tested and approved to the following safety standards for medical equipment:

Medical Electrical Equipment, Part 1 General Requirements – EN60601-1: 1990+A1+A2
Medical Electrical Equipment, Part 1 General Requirements – IEC60601-1: 1998+A1+A2
Medical Electrical Equipment, Part 1 General Requirements
Section 1.2 Collateral standard: Electromagnetic Compatibility-EN60601-1-2
Medical Electrical Equipment, Part 1 General Requirements for Safety
Section 1.4 Collateral Standard: Programmable Electrical Medical Systems-IEC60601-1-4:1996
Medical Electrical Equipment, Part 1 General Requirements-Can/CSA C22.2 No.606101-M90
Medical Electrical Systems-IEC 606601-1-1:1993+A1

540 Alpha Drive • Pittsburgh, PA 15238 U.S.A. • (412) 963-1988 FAX (412) 963-0610

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2002

Ms. Mary Anne Dell
CAPINTEC, Inc.
540 Alpha Drive
PITTSBURGH PA 15238 USA

Re: K020150
Trade/Device Name: CRC 15BT Calibrator
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: 90 KPT
Dated: May 13, 2002
Received: May 14, 2002

Dear Ms. Dell:

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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

K020150

Appendix 2

Indications for Use Form

Page ____ of ____

510(k) Number (if known):

Device Name: CRC 15BT

Indications For Use: The CRC 15BT dose calibrator is intended to be used by trained medical physicists, or qualified technologists to measure the activity or output of radioactive brachytherapy sources, including HDR, LDR and IVBT sources.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020150