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CAPINTEC, INC.

July 9, 2010

RE: Summary of Safety and Effectiveness Information for the Capintec CRC 55t series.

Capintec's CRC 55t series dose calibrators are designed for measurement of radioactive materials used in nuclear medicine, therapy, laboratory tests, and research applications. The unit is intended for use by trained nuclear medicine technologists, nuclear medicine physicians, radiopharmacists, or medical physicists for diagnostic, in vitro, and therapeutic applications.

The CRC 55t series uses the same principles of operation, same basic electronic circuitry, and same detector technology as the predicated device, CRC 25 series. The basic detection, measurement process, design concepts, functionality, calculations, algorithms, and response remain the same as the predicate device. There are no differences in intended use or effectiveness. The 55t replaces the traditional keypad interface with a larger color touch screen display. The CRC 55t provides enhanced user interface features associated with newer touch screen technology. In addition, the CRC 55t provides an expanded MCA for isotope identification. The predicate device contains 6 fixed channels which provides only preliminary information. The CRC 55t includes a 256 channel MCA which permits spectral identification.

The predicate devices, Capintec dose calibrator lines, upon which the CRC 55t is based, have a long history of over 30 years of safe, reliable, and effective use in the field. The addition of a larger color touch screen interface enhances safety and effectiveness by providing improved visibility, easier alphanumeric data input, better graphic displays, more preset functions, and improved reports. The enhanced MCA provides improved isotope identification. The CRC 55t family of dose calibrators have been tested and approved to the following EMC and electrical safety standards for laboratory equipment:

- IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1 General Requirements
- IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 2 Particular Requirement for In Vitro Diagnostic Equipment
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility – Requirements and tests
- UL 61010A-1 Electrical Equipment for Laboratory Use; Part 1: General Requirements
- CAN/CSA-C22.2 No. 61010-1-04 Standard for Safety Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
- CAN/CSA-C22.2 No. 61010-2-101-04 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-101: Particular Requirements for In Vitro Diagnostics (IVD) Medical Equipment

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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

Ms. Mary Anne Dell
Vice President, Manufacturing
Capintec, Inc.
620 Alpha Drive
PITTSBURG PA 15238

AUG - 9 2010

Re: K101452
Trade/Device Name: CRC 55t Series
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: KPT and JAQ
Dated: July 27, 2010
Received: July 28, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101452

Appendix # 5

Indications for Use Form

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510(k) Number K101452

Device Name: CRC 55t series

Indications For Use: The CRC 55t series, which includes the standard 55tR dose calibrator, reduced pressure chamber (CRC 55tPET) and well counter (CRC55tW), is intended to be used by qualified nuclear medicine technologists, nuclear medicine physicians, and radiopharmacists to measure a wide range of radiopharmaceuticals and radioactive materials, including high energy beta and gamma emitters for diagnostic, therapeutic, or in vitro laboratory tests. It is also designed for use by trained medical physicists to measure the output of most radioactive brachytherapy sources, including LDR, HDR, and IVBT sources. All brachytherapy sources must be measured in the appropriate source holder. The well counter is designed for measurement of low activity radioactive sources or solutions including in vitro laboratory test applications. This device is also used in numerous research applications for measurement of radioactive materials.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101452