Capintec, Inc.
% Ms. Mary Anne Yusko
VP Regulatory Affairs
7 Vreeland Road
FLORHAM PARK NJ 07932

September 12, 2019

Re: K192199
Trade/Device Name: CRC PC Smart Chamber K1
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide Dose Calibrator
Regulatory Class: Class II
Product Code: KPT
Dated: August 14, 2019
Received: August 15, 2019

Dear Ms. Yusko:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192199

Device Name

CRC PC with Smart Chamber K1

Indications for Use *(Describe)*
The CRC PC Smart Chamber K1 is intended to be used by qualified nuclear medicine technologists, nuclear medicine physicians, and radiopharmacists to measure radiopharmaceuticals, including high energy beta and gamma emitters for diagnostic applications. The CRC PC Smart Chamber K1 is intended to be used only with the TEMA Karls 100 radiopharmaceutical dose administration system.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CAPINTEC, INC.

August 9, 2019

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

Device Trade Name:	CRC PC Smart Chamber K1
Common or Usual Name:	Radioisotope Dose Calibrator
Classification Name:	Radioisotope dose calibrator (21 CFR 982.1360)
Regulatory Class:	II
Product Code:	KPT
Predicate Device:	The CRC-PC Smart Chamber K1 dose calibrator is a modification of the predicate device, CRC-PC Smart Chamber series, which received FDA clearance under 510(k) number K141413

Manufacturer: Capintec, Inc.
7 Vreeland Road
Florham Park, New Jersey 07932 USA
Phone: 201-825-9500 FAX 201-825-1336

Product Description: The Capintec CRC PC Smart Family of dose calibrators are sealed, pressurized reentrant well style ionization chambers which use a networked PC as the user interface. The CRC PC Smart Chamber K1 is modified CRC PC Smart Chamber, which has been shortened in height to fit into the Karl 100 Dose Administration System, which is manufactured by TEMA.

Indications for Use: The CRC PC Smart Chamber K1 is intended to be used by qualified nuclear medicine technologists, nuclear medicine physicians, and radiopharmacists to measure radiopharmaceuticals, including high energy beta and gamma emitters for diagnostic applications. The CRC PC Smart Chamber K1 is intended to be only with the TEMA Karl 100 radiopharmaceutical dose administration system.

Comparison to Predicate Device: The CRC-PC Smart Chamber K1 is identical to the predicate device, the CRC-PC Smart Chamber, in terms of scientific technology, method of operation, radiation detector design, calibration, measurement processes, and basic electronic circuitry. There are two design main differences between the two devices: vertical dimension change and deactivation of some software features found in the CRC-PC Smart Chamber, The CRC-PC Smart Chamber K1 height is reduced from the standard chamber height of 18.1 inches to 12.5 inches. The reduced height allows it to fit without any other modification into the Karl 100 dose administration system. It will be used in only one geometric configuration, 3 ml of solution in the Karl 100 sample cartridge. This assures reproducible geometry. Since there is only one geometry, Moly Assay has been removed from the software.

Safety and Effectiveness: Risk assessment confirms that all identified risks were either mitigated or are within acceptable limits. Verification and validation testing confirmed the CRC-PC Smart Chamber K1 meets all stated specifications and functions as expected.

CRC PC Smart Chamber K1, is one of many Capintec dose calibrators which utilize the same ionization chamber design. These dose calibrators have a long history of over 40 years of safe, reliable, and effective use in the field. The CRC PC family of dose calibrators, including the CRC PC Smart Chamber K1, is approved to the following EMC and electrical safety standards for medical equipment:

IEC 60601-1-2 (2007) Ed 3: Medical Electrical Equipment – Part 1 General Requirements for Safety – Section 1.2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1 Issued: 2005 Ed: 3: Medical electrical equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 2010 3rd Edition: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 62366:2007 (Ed 1). Medical device application of usability engineering to medical devices

Conclusion: Based on the above summary, Capintec concludes that the CRC PC Smart Chamber K1 is substantially equivalent to its predicate device.