



Canon Medical Systems Corporation
% Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

April 23, 2021

Re: K203314

Trade/Device Name: Cartesion Prime (PCD-1000A/3) V10.8
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: March 23, 2021
Received: March 24, 2021

Dear Mr. Tadeo:

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

Indications for Use

510(k) Number (if known)

K203314

Device Name

Cartesion Prime (PCD-1000A/3) V10.8

Indications for Use (Describe)

The device is a diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT component produces cross-sectional images of the body by computer reconstruction of X-ray transmission data. The PET component images the distribution of PET radiopharmaceuticals in the patient body. The PET component utilizes CT images for attenuation correction and anatomical reference in the fused PET and CT images.

This device is to be used by a trained health care professional to gather metabolic and functional information from the distribution of the radiopharmaceutical in the body for the assessment of metabolic and physiologic functions. This information can assist in the evaluation, detection, localization, diagnosis, staging, restaging, follow-up, therapeutic planning and therapeutic outcome assessment of (but not limited to) oncological, cardiovascular, neurological diseases and disorders. Additionally, this device can be operated independently as a whole body multi-slice CT scanner.

AiCE-i for PET is intended to improve image quality and reduce image noise for FDG whole body data by employing deep learning artificial neural network methods which can explore the statistical properties of the signal and noise of PET data. The AiCE algorithm can be applied to improve image quality and denoising of PET images.

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.

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
PRASStaff@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."



CANON MEDICAL SYSTEMS USA, INC.

*Made For life***510(k) SUMMARY****1. SUBMITTER'S NAME:**

Fumiaki Teshima
Senior Manager, Quality Assurance Department
Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

2. ESTABLISHMENT REGISTRATION:

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON:

Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

4. Date Prepared:

November 6, 2020

5. TRADE NAME(S):

Cartesion Prime (PCD-1000A/3) V10.8

6. COMMON NAME:

System, X-ray, Computed Tomography
System, Emission Computed Tomography

7. DEVICE CLASSIFICATION:

Class II (per 21 CFR 892.1750, Computed Tomography X-ray System and 21 CFR §892.1200, Emission Computed Tomography System)

8. PRODUCT CODE / DESCRIPTION:

90JAK / Computed Tomography X-Ray System
90KPS / Emission Computed Tomography System

9. PERFORMANCE STANDARD:

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

10. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Cartesion Prime, PCD-1000A, V10.7	Canon Medical Systems USA	21 CFR 892.1200	Emission Computed Tomography System	KPS	K202349	October 15, 2020

11. REASON FOR SUBMISSION:

Modification of a cleared device

12. DEVICE DESCRIPTION:

Cartesion Prime (PCD-1000A) V10.8 system combines a high-end CT and a high-throughput PET designed to acquire CT, PET and fusion images. The high-end CT system is a multi-slice helical CT scanner with a gantry aperture of 780 mm and a maximum scan field of view (FOV) of 700 mm. The high-throughput PET system has a digital PET detector utilizing SiPM sensors with temporal resolution of <280 ps (263 ps typical). **Cartesion Prime (PCD-1000A) V10.8** is intended to acquire PET images of any desired region of the whole body and CT images of the same region (to be used for attenuation correction or image fusion), to detect the location of positron emitting radiopharmaceuticals in the body with the obtained images. This device is used to gather the metabolic and functional information from the distribution of radiopharmaceuticals in the body for the assessment of metabolic and physiologic functions. This information can assist research, detection, localization, evaluation, diagnosis, staging, restaging, follow-up of diseases and disorders, as well as their therapeutic planning, and therapeutic outcome assessment. This device can also function independently as a whole body multi-slice CT scanner.

The subject device incorporates the latest reconstruction technology, AiCE-i for PET (Advanced Intelligent Clear-IQ Engine- integrated), intended to improve image quality and reduce image noise for FDG whole body data by employing deep learning artificial neural network methods which can more fully explore the statistical properties of the signal and noise of PET data. The AiCE algorithm will be able to better differentiate signal from noise and can be applied to improve image quality and denoising of PET images.

13. INDICATIONS FOR USE:

The device is a diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT component produces cross-sectional images of the body by computer reconstruction of X-ray transmission data. The PET component images the distribution of PET radiopharmaceuticals in the patient body. The PET component utilizes CT images for attenuation correction and anatomical reference in the fused PET and CT images.

This device is to be used by a trained health care professional to gather metabolic and functional information from the distribution of the radiopharmaceutical in the body for the assessment of metabolic and physiologic functions. This information can assist in the evaluation, detection, localization, diagnosis, staging, restaging, follow-up, therapeutic planning and therapeutic outcome assessment of (but not limited to) oncological, cardiovascular, neurological diseases and disorders. Additionally, this device can be operated independently as a whole body multi-slice CT scanner.

AiCE-i for PET is intended to improve image quality and reduce image noise for FDG whole body data by employing deep learning artificial neural network methods which can explore the statistical properties of the signal and noise of an input PET image. The AiCE algorithm can be applied to improve image quality and denoising of PET images.

14. SUBSTANTIAL EQUIVALENCE:

Cartesion Prime (PCD-1000A) V10.8, is substantially equivalent to the primary predicate device, **Cartesion Prime, PCD-1000A, V10.7** which received premarket clearance under K191582 and is marketed by Canon Medical Systems USA. Both systems have the same indications for use and intended use. The **Cartesion Prime, PCD-1000A, V10.7**, incorporates modifications to the cleared device including implementation of AiCE-i for PET images, PET 1-mm reconstruction and Dynamic PET Acquisition/Reconstruction. These changes do not affect the safety or efficacy of the cleared device, as demonstrated in performance testing. The method of operation and manufacturing process for the Cartesion Prime remain unchanged from the cleared device. See below for a brief comparison of the technological characteristics between the subject and the predicate device:

Item	Cartesion Prime (PCD-1000A/3) V10.8	Cartesion Prime, PCD-1000A, V10.7
510(k) Number	This submission	K202349
Advanced Intelligent Clear-IQ Engine- integrated for PET [AiCE-i for PET]	Option	N/A
PET 1-mm Reconstruction System	Option	N/A
Dynamic PET Acquisition/Reconstruction System	Option	N/A

15. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the following standards IEC60601-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-1-9, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, IEC61675-1, NEMA XR-25, NEMA XR-26, NEMA XR-29 and NEMA NU-2. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

16. TESTING

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrates that the established specifications for the device have been met. Bench testing was conducted and it was determined that use of CaLM Reconstruction resulted in images with improvements to image quality, quantification accuracy, count dependency, and preservation of quantification.

A series of bench tests were conducted to support marketing claims associated with image quality, quantification accuracy, count dependency, and preservation of quantification. As demonstrated in these studies, AiCE-i for PET significantly improved Signal to Noise Ratio, improved quantification at the same noise, reduced the count rates while preserving noise, and that it preserves average SUV and activity concentration of the image.

A series of bench tests were conducted to support marketing claims associated with CaLM image quality, quantification accuracy, CaLM count dependency, and CaLM preservation of quantification. As demonstrated in these studies, CaLM improved Signal to Noise Ratio, improved contrast compared to OSEM+ Gaussian at equivalent noise level, and reduced the scan duration or equivalently the counts compared to OSEM+Gaussian postfilter while preserving noise.

Performance Testing – Bench AiCE-i for PET Evaluations

NEMA NU 2-2018 Image Quality

Through the phantom experiment following NEMA NU 2-2018, the basic performance of AiCE-i for PET is measured. (Indices Measured: Contrast Recovery Coefficient (CRC), Background Variability (BGV), and Lung Residual Error.)

AiCE-i for PET Phantom Artifact Check

By visually inspecting the IEC Body phantom images, it is confirmed that AiCE-i for PET does not create any artifacts.

AiCE-i for PET Quantification Accuracy

A phantom study was conducted to confirm that AiCE-i for PET yields higher contrast than OSEM+Gaussian post-filtering at the same noise level.

AiCE-i for PET Preservation of Quantification

The study confirmed that AiCE-i for PET does not change over all quantification of reconstructed image of IEC Body Phantom. (Indices Measured: Background mean, Sum of SUV of the sphere slice, and Sum of SUV of the entire IEC Body Phantom.)

AiCE-i for PET Clinical Data Check

The visual inspection, including slice by slice comparison of AiCE-i for PET and No-Postfiltered image as well as OSEM+Gaussian 6mm image, confirmed AiCE-i for PET creates no artifact. (Indices Measured: Liver SUV, Live SD, Hotspot SUV, Hotspot SUV_{max}, and Slice-by-Slice SUV of every slice in the volume)

AiCE-i for PET PSNR Measurements

Using the clinical data of long scan duration that is not used in the DCNN training process, it was confirmed that AiCE-i for PET images show higher similarity to the long duration image compared to OSEM + Gaussian Postfilter images. (Indices Measured: Peak Signal to Noise Ratio (PSNR))

Performance Testing – Clinical AiCE-i for PET Evaluation

Three physicians having at least 20 years of experience in nuclear medicine reviewed the AiCE-i for PET images of five patients. All three physicians determined that all five AiCE-i for PET images were of diagnostic quality. Overall image quality, image sharpness and image noise were determined to be either improved or significantly improved in AiCE-i for PET images when compared to Gaussian images, with the exception of image noise, where one physician determined that the noise in AiCE-i for PET images is about the same as Gaussian images.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of this submission.

Cybersecurity documentation, per the FDA cybersecurity premarket guidance document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” issued on October 2, 2014, is also included as part of this submission.

Additionally, testing of the subject device was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

This 510(k) submission was prepared based upon the FDA Guidance for Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems.

17. CONCLUSION

Cartesion Prime (PCD-1000A) V10.8, performs in a manner that is similar to and is intended for the same use as the predicate device, as indicated in product labeling. Based upon this information, conformance to standards, successful completion of software validation, application of risk management and design controls and the performance data presented in this submission it is concluded that the subject device is substantially equivalent in safety and effectiveness to the predicate device.