



December 1, 2025

Canon Medical Systems Corporation  
% Yoshiaki Cook  
Sr. Manager, Regulatory Affairs  
Canon Medical Systems, USA  
2441 Michelle Drive  
Tustin, California 92780

Re: K251370

Trade/Device Name: Cartesion Prime (PCD-1000A/3) V10.21  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission Computed Tomography System  
Regulatory Class: Class II  
Product Code: KPS, JAK  
Dated: October 8, 2025  
Received: October 8, 2025

Dear Yoshiaki Cook:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.  
Assistant Director  
DHT8C: Division of Radiological  
Imaging and Radiation Therapy Devices  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251370

?

Please provide the device trade name(s).

?

Cartesion Prime (PCD-1000A/3) V10.21

Please provide your Indications for Use below.

?

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.

Deviceless PET Respiratory gating system, for use with Cartesion Prime PET-CT system, is intended to automatically generate a gating signal from the list-mode PET data. The generated signal can be used to reconstruct motion corrected PET images affected by respiratory motion. In addition, a single motion corrected volume can automatically be generated. Resulting motion corrected PET images can be used to aid clinicians in detection, localization, evaluation, diagnosis, staging, restaging, follow-up of diseases and disorders, radiotherapy planning, as well as their therapeutic planning, and therapeutic outcome assessment. Images of lesions in the thorax, abdomen and pelvis are mostly affected by respiratory motion. Deviceless PET Respiratory gating system may be used with PET radiopharmaceuticals, in patients of all ages, with a wide range of sizes, body habitus, and extent/type of disease.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

**510(k) SUMMARY**

K251370

- 1. SUBMITTER'S NAME:**  
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Canon Medical Systems Corporation  
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- 2. ESTABLISHMENT REGISTRATION:**  
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- 3. OFFICIAL CORRESPONDENT/CONTACT PERSON:**  
Yoshiaki Cook  
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Canon Medical Systems USA, Inc  
2441 Michelle Drive  
Tustin, CA 92780  
(657) 270-5595
- 4. DATE PREPARED:**  
May 2, 2025
- 5. TRADE NAME(S):**  
Cartesion Prime (PCD-1000A/3) V10.21
- 6. COMMON NAME:**  
System, Emission Computed Tomography  
System, X-ray, Computed Tomography System
- 7. DEVICE CLASSIFICATION:**  
Classification Name: Emission Computed Tomography X-ray system  
Regulation Number: 21 CFR §892.1200  
Regulatory Class: Class II  
  
Classification Name: Computed Tomography X-ray system  
Regulation Number: 21 CFR §892.1750  
Regulatory Class: Class II

**8. PRODUCT CODE:**

90KPS  
90JAK

**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/3) V10.15	Canon Medical Systems USA	21 CFR 892.1200	Emission Computed Tomography System	KPS	K231748	September 12, 2023

**11. REASON FOR SUBMISSION:**

Modification of a cleared device

**12. DEVICE DESCRIPTION:**

**The Cartesion Prime (PCD-1000A/3) V10.21** 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 < 250 ps (238 ps typical). **Cartesion Prime (PCD-1000A/3) V10.21** 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 compared to conventional PET imaging reconstruction.

A Deviceless PET Respiratory gating system has been implemented for use with the subject device. With this subject device, respiration is extracted using a pre-trained neural network. Respiratory-gated reconstruction is performed at a speed equal to or faster than that with "Normal".

**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 PET data. The AiCE algorithm can be applied to improve image quality and denoising of PET images.

Deviceless PET Respiratory gating system, for use with Cartesion Prime PET-CT system, is intended to automatically generate a gating signal from the list-mode PET data. The generated signal can be used to reconstruct motion corrected PET images affected by respiratory motion. In addition, a single motion corrected volume can automatically be generated. Resulting motion corrected PET images can be used to aid clinicians in detection, localization, evaluation, diagnosis, staging, restaging, follow-up of diseases and disorders, radiotherapy planning, as well as their therapeutic planning, and therapeutic outcome assessment. Images of lesions in the thorax, abdomen and pelvis are mostly affected by respiratory motion. Deviceless PET Respiratory gating system may be used with PET radiopharmaceuticals, in patients of all ages, with a wide range of sizes, body habitus, and extent/type of disease.

**14. SUBSTANTIAL EQUIVALENCE:**

The **Cartesion Prime (PCD-1000A/3) V10.21** is substantially equivalent to Cartesion Prime (PCD-1000A/3) V10.15, which received premarket clearance under K231748, and is currently marketed by Canon Medical Systems USA.

The subject and predicate devices are the same with the only differences being, expansion of the use of AiCE-i for PET with pediatric imaging and allowing for user-selectable intensity settings as opposed to simply selecting 'on/off', and implementation of a deep-learning artificial neural network based Deviceless PET Respiratory gating system that analyzes respiratory motion in order to reconstruct motion-corrected PET images.

A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	Predicate Device
Device Name, Model Number	Cartesion Prime (PCD-1000A/3) V10.21	Cartesion Prime (PCD-1000A/3) V10.15
510(k) Number	This submission	K231748
Deviceless PET Respiratory gating system	Mode Setting: AI	Mode Setting: Normal
AiCE-i for PET	Pediatric Imaging: Available  Intensity Settings: Smooth, Standard, Sharp	Pediatric Imaging: Not Available  Intensity Settings: ON/OFF

**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, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC81001-5-1, IEC62366-1, 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 activities conducted through bench testing demonstrate that the established specifications for the device have been met.

**16.a. AiCE-i for PET (AiCE2)**

This feature employs a deep learning artificial neural network method to improve image quality and denoise PET images. This algorithm was developed to explore the statistical properties of signal and noise of input PET images and was trained to automatically adapt to different noise levels to produce consistently high-quality images. The improvement to the algorithm implemented in AiCE2 incorporated a different training methodology relative to the previous version, in order to achieve the development of Sharp, Standard and Smooth intensity settings, although the training data remained identical. From the original training dataset, a subset was assembled using FDG studies of sixteen (16) cancer patients (BMI: 19.5-34.5) over half of which were acquired from the U.S. and selected to cover a wide range of representative anatomy.

***Performance Testing – AiCE for PET Pediatric Use***

A series of bench tests was conducted to support marketing claims associated with the use of AiCE for PET for pediatric imaging. This optional pediatric imaging function demonstrates equivalence to the currently cleared imaging methods with regards to: Contrast Recovery Coefficient (CRC), Background Variability (BGV) and Contrast to Noise Ratio (CNR), absence of artifacts, and the quantitativity ( $SUV_{mean}$ ) for the intended pediatric use.

### ***Performance Testing – AiCE for PET Image Intensity***

A series of bench tests was conducted to support marketing claims associated with the tiered imaging intensity function (as opposed to the previously cleared “on/off” function). This method has been demonstrated to be substantially equivalent to the current method of image intensity, and, with respect to quantitative parameters such as accuracy of SUV (max and mean) and tumor volume, is improved over the current image intensity setting.

### ***Performance Testing - Substantial equivalence between AiCE2 and AiCE1***

Phantom testing in accordance with NEMA NU-2, Section 7 was conducted in order to compare the Sharp, Standard and Smooth intensity settings available with AiCE2 to AiCE1, using a 10 mm sphere target to measure SUV<sub>mean</sub>, background variability (BGV), contrast recovery coefficient (CRC), and signal to noise ratio (SNR (with Std error)) and compare the values between both versions of AiCE-i for PET. The results across all indices demonstrated either equivalence or improvement by AiCE2.

Additional phantom studies were conducted using 1) the Adult and Pediatric NEMA phantoms to confirm that the 10 mm CRC, BGV, and CNR of the Sharp, Standard and Smooth intensity settings available with AiCE2 are substantially equivalent to AiCE1, 2) the Small Pool phantom in order to confirm that the quantified SUV<sub>mean</sub> is equivalent between both versions, and 3) the Pediatric NEMA phantom and Small Pool Phantom to confirm that there are no artifacts in the images reconstructed with either version of AiCE-i for PET. The results of these studies demonstrated equivalent performance between AiCE1 and AiCE2, with respect to the preservation of contrast and improving noise levels relative to conventional imaging methods.

### ***Performance Testing – Representative Clinical Images***

Three (3) physicians having at least 20 years of experience in nuclear medicine evaluated the performance of Sharp, Smooth, and Standard intensity settings of AiCE2 using ten (10) PET DICOM clinical 18F-FDG whole body cases, compared to OSEM and Gaussian filter methods. All three physicians reported that AiCE2 images at all three intensity settings were of diagnostic quality and consistent across all 10 cases, determined to perform better with respect to overall image quality and image sharpness, as well as exhibit lower image noise compared to the predicate methods.

This validation dataset was entirely independent of the dataset used for training the algorithm during its development and was acquired from a total of 10 male and female patients and selected to cover characteristics common to the intended U.S. patient population by including a range of body mass indices, from 20.5 to 38.7, and by the inclusion of cases characterized by small lesions with lower level of FDG uptake.

#### **16.b. Deviceless PET Respiratory gating system (DRG2)**

This feature employs an algorithm which uses a neural network to extract motion information from acquired PET data and to generate a corresponding gating signal which can be used to reduce the effects of respiratory motion, thereby improving the image quality of reconstructed PET images. This neural network was trained on FDG studies of 27 cancer patients (BMI: 19.82-45.35, 3 instances unknown) acquired entirely from the U.S. and selected to be representative of both sexes as well as a wide range of scan characteristics.

***Performance Testing – Deviceless PET Respiratory gating System Operational Mode***

A series of bench tests was conducted to support marketing claims associated with the AI operating system of the Deviceless PET Respiratory gating system. This system has been demonstrated to be substantially equivalent to the current method of respiratory gating, using an external device, and, with respect to quantitative parameters such as accuracy of SUV (max and mean) and tumor volume, is improved over the current device-based gating method.

***Performance Testing – Substantial equivalence between DRG2 and DRG1***

This evaluation used reconstructed clinical raw data acquired from 11 total male and female patients (BMI: 17.7-38.7), each with a representative lesion and covering a range of breathing rates. This dataset was entirely independent of the dataset used for training the algorithm. The primary objective of this evaluation was to demonstrate equivalency between deviceless PET respiratory gating with the new AI mode setting (DRG2) and predicate deviceless PET respiratory gating functionality (DRG1), by comparison of the quantified outputs on high uptake regions (e.g., lesions) of the reconstructed datasets. By satisfying all prespecified criteria, it was demonstrated that DRG2 performs with substantial equivalence to DRG1.

***Performance Testing – Representative Clinical Images***

Three (3) physicians having at least 20 years of experience in nuclear medicine evaluated the respiratory gated images of ten (10) patients using Deviceless PET Respiratory gating system, non-gated images and those using device-base gating. All three (3) physicians determined that all images were of diagnostic quality and deviceless gated images demonstrated similar or better performance as device-based gated images and resulted in better motion correction compared to non-gated images.

This validation dataset was entirely independent of the dataset used for training the algorithm during its development and consisted of 10 total male and female patients, selected to cover characteristics common to the intended U.S. patient population, including a range of body mass indices, from 18.9 to 38.7, and cases including representative tumors and lesions.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023, is included in this submission. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation, per the FDA guidance document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”, issued on September 27, 2023, was included in this submission.

**17. CONCLUSION**

The **Cartesion Prime (PCD-1000A/3) V10.21** performs in a manner 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 has demonstrated substantial equivalence to the predicate device and is as safe and effective for its intended use.