September 12, 2023

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

Re: K231748
Trade/Device Name: Cartesion Prime (PCD-1000A/3) V10.15
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 14, 2023
Received: June 15, 2023

Dear Orlando 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231748

Device Name
Cartesion Prime (PCD-1000A/3) V10.15

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.

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.

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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510(k) SUMMARY

K231748

1. **SUBMITTER'S NAME:**
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   Senior Manager, Quality Assurance Department
   Canon Medical Systems Corporation
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   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:**
   June 12, 2023

5. **TRADE NAME(S):**
   Cartesion Prime (PCD-1000A/3) V10.15

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/3) V10.8 (*Primary Predicate*)	Canon Medical Systems USA	21 CFR 892.1200	Emission Computed Tomography System	KPS	K203314	April 23, 2021
PET Digital Gating (*Reference Predicate*)	GE Medical Systems, LLC	21 CFR 892.1200	Emission Computed Tomography System	KPS	K180318	April 11, 2018

11. REASON FOR SUBMISSION:

Modification of a cleared device

12. DEVICE DESCRIPTION:

Cartesion Prime (PCD-1000A/3) V10.15 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/3) V10.15** 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.

A Deviceless PET Respiratory-gating System is being implemented with the subject device. This 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.

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:

Cartesion Prime (PCD-1000A/3) V10.15, is substantially equivalent to the primary predicate device, **Cartesion Prime (PCD-1000A/3) V10.8** which received premarket clearance under K203314 and is marketed by Canon Medical Systems USA. Both systems have the same intended use. The **Cartesion Prime (PCD-1000A/3) V10.15**, incorporates modifications to the cleared device including implementation of Deviceless PET Respiratory-gating system. 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) V10.15 with Deviceless PET Respiratory-gating system	Cartesion Prime (PCD-1000A/3) V10.8	PET Digital Gating
510(k) Number	This submission	K203314	K180318
Predicate Device Type	N/A	Primary	Reference
PET Specifications			
• Count rate peak NECR	> 160 kcps	> 160 kcps	N/A
• vBT (Variable Bed Time)	Available	Available	N/A
• CaLM (Clear adaptive Low-noise method)	Available	Available	N/A
PET Detector			
• Sensor	SiPM	SiPM	N/A
CT Scan Performance			
• Scan system	360° continuous rotate/rotate	360° continuous rotate/rotate	N/A
• Rated output	Max. 60 kW (Max.72 kW, optional	Max. 60 kW (Max.72 kW, optional)	N/A
• X-ray tube voltage	80/100/120/135 kV	80/100/120/135 kV	N/A
• X-ray tube current	10-600 mA	10-600 mA	N/A
• X-ray tube cooling rate	1,386 kHU/min (max.)	1,386 kHU/min (max.)	N/A
• Advanced Intelligent Clear-IQ Engine- integrated [AiCE-i]	Available	Available	N/A
PET Respiratory-gating			
• Method	Deviceless	Device-based	Deviceless
• Hardware	No additional hardware required	Additional hardware required	No additional hardware required
• Device Setup	No direct user interaction	Direct user interaction required to set up external device	No direct user interaction
• Compatible motion compensation techniques able to utilize respiratory triggers	Gated with device	Gated with device	Gated, Q.Static, and Q.Freeze
• Reference protocols for respiratory gating	Reference protocols provided on the system	Reference protocols provided on the system	Reference protocols provided on the system
• Triggering operating principle	Triggers generated from the waveform obtained by applying the principal component analysis on the characteristic feature map extracted from the PET image data	Based upon external patient movement as determined by external hardware device	Triggers generated utilizing software algorithm (PCA) for evaluation motion of internal anatomy visualized in the PET image data.

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, 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.

Performance Testing – Bench for Deviceless PET respiratory-gating

A series of bench tests were conducted to support marketing claims associated with the new 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 – Clinical Images Using Deviceless PET Respiratory-gating system

Three physicians having at least 20 years of experience in nuclear medicine reviewed the respiratory gated images of 10 patients using Deviceless PET Respiratory-gating system, non-gated images and those using device-base gating. All three physicians determined that all images were of diagnostic quality and images with deviceless had better or same performance as non-gated images or device-based gated 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/3) V10.15, 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.