Canon Medical Systems Corporation
% Orlando Tadeo Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive
TUSTIN CA 90630

October 15, 2020

Re: K202349
Trade/Device Name: Cartesion Prime, PCD-1000A, V10.7
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: August 17, 2020
Received: August 18, 2020

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202349

Device Name

Cartesion Prime, PCD-l000A, Vl0.7

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 . Additiona lly, this device can be operated independently as a whole body multi-slice CT scanner.

Type of Use *(Select one or both, as applicable)*

X 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.

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K202349

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Canon Medical Systems
   1385 Shimoishigami
   Otawara-Shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT:**
   Fumiaki Teshima
   Senior Manager, Quality Assurance Department

3. **ESTABLISHMENT REGISTRATION:**
   9614698

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

5. **Date Prepared:**
   August 17, 2020

6. **TRADE NAME(S):**
   Cartesion Prime, PCD-1000A, V10.7

7. **COMMON NAME:**
   System, X-ray, Computed Tomography
   System, Emission Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750, Computed Tomography X-ray System and 21 CFR §892.1200, Emission Computed Tomography System)

9. PRODUCT CODE / DESCRIPTION:

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

10. PERFORMANCE STANDARD:

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

11. PREDICATE DEVICE:

Product	**Marketed by**	**Regulation Number**	**Regulation Name**	**Product Code**	**510(k) Number**	**Clearance Date**
Cartesion Prime, PCD-1000A *Primary Predicate Device*	Canon Medical Systems USA	21 CFR 892.1200	Emission Computed Tomography System	KPS	K191582	August 13, 2019
Celesteion, PCA-9000A/3, v6.5 *Reference Predicate Device*	Canon Medical Systems USA	21 CFR 892.1200	Emission Computed Tomography System	KPS	K181646	November 16, 2018

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

Cartesion Prime, PCD-1000A, V10.7 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 scanning field of 700 mm. The high-throughput PET system has a digital PET detector utilizing SiPM sensors with temporal resolution of <280 ps. **Cartesion Prime, PCD-1000A, V10.7** 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.

14. 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.

15. SUBSTANTIAL EQUIVALENCE:

Cartesion Prime, PCD-1000A, V10.7, is substantially equivalent to the primary predicate device, **Cartesion Prime, PCD-1000A**, 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 a respiratory gating system and cardiac gating. 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, V10.7**	**Cartesion Prime, PCD-1000A**
510(k) Number	This submission	K191582
Count rate peak NECR	> 160 kcps	> 130 kcps@<12 kBq/ml
Count rate peak true	> 600 kcps	> 300 kcps@<12 kBq/ml
Variable bed time (vBT)	Available	Available
CaLM (Clear adaptive Low-noise Method Reconstruction)	Available	Available

Previously cleared software option being implemented to the modified device:

PET Respiratory Gating System (NKRS-001A)	Previously cleared under K181646
PET Cardiac Gating (NHEG-001A)	Previously cleared under K181646

16. 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.

17. 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. Additional bench testing was conducted and it was determined that use of CaLM Reconstruction resulted in images with improved Signal-to-Noise Ratio, and reduced noise while preserving detail and contrast, Point Spread Function (PSF) correction resulted in images with better contrast, reduced noise and improved spatial resolution, and that using PET Respiratory and Cardiac Gating improved image quality and allowed for the acquisition of multiple phase data sets.

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.

18. CONCLUSION

Cartesion Prime, PCD-1000A, V10.7, 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.