



November 16, 2018

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

Re: K181646  
Trade/Device Name: Celesteion, PCA-9000A/3, V6.5  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission Computed Tomography System  
Regulatory Class: Class II  
Product Code: KPS, JAK  
Dated: October 17, 2018  
Received: October 18, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 "Rob A. Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for  
Robert A. Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K 181646

Device Name

Celesteion, PCA-9000A/3, v6.5

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, diagnosis, therapeutic planning and therapeutic outcome assessment of (but not limited to) cancer, cardiovascular disease and brain dysfunction. Additionally, this device can be operated independently as a whole body multi-slice CT scanner.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.\***

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CANON MEDICAL SYSTEMS USA, INC.

*Made For life*

**510(k) SUMMARY**

**1. SUBMITTER'S NAME:**

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**2. OFFICIAL CORRESPONDENT:**

Naofumi Watanabe  
Senior Manager, Regulatory Affairs and Vigilance

**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:**

June 21, 2018

**6. TRADE NAME(S):**

Celesteion, PCA-9000A/3, V6.5

**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 |
|-------------------------------|---------------------------|-------------------|-------------------------------------|--------------|---------------|----------------|
| Celesteion, PCA-9000A/3, v6.4 | Canon Medical Systems USA | 21 CFR 892.1200   | Emission Computed Tomography System | KPS          | K170490       | June 1, 2017   |

**12. REASON FOR SUBMISSION:**

Modification to existing device

**13. DEVICE DESCRIPTION:**

**Celesteion, PCA-9000A/3, V6.5**, is a large bore, TOF, PET-CT system, which combines a high-end CT system with a high-throughput PET system. The high-end CT system is a multi-slice helical CT scanner with a gantry aperture of 900 mm and a maximum scanning field of 700 mm. The high-throughput PET system has a time of flight (TOF) detector with temporal resolution of 450 ps.

**Celesteion, PCA-9000A/3, V6.5** 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, diagnosis, 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,

diagnosis, therapeutic planning and therapeutic outcome assessment of (but not limited to) cancer, cardiovascular disease and brain dysfunction. Additionally, this device can be operated independently as a whole body multi-slice CT scanner.

#### 15. SUBSTANTIAL EQUIVALENCE:

**Celesteion, PCA-9000A/3, V6.5**, is substantially equivalent to **Celesteion, PCA-9000A/3, V6.4**, which received premarket clearance under K170490 and is marketed by Canon Medical Systems USA. The **Celesteion, PCA-9000A/3, V6.5**, incorporates modifications to the cleared device including a modification to the existing respiratory gating system to improve workflow, implementation of a new PET ECG gating system, and two new features, Variable Bed Time (vBT) and Clear Adaptive Low-Noise Method (CaLM) 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 Celesteion remain unchanged from the cleared device. See below for a brief comparison of the technological characteristics between the subject and the predicate device:

| Item                                                  | Celesteion, PCA-9000A/3, V6.5      | Celesteion, PCA-9000A/3, V6.4 |
|-------------------------------------------------------|------------------------------------|-------------------------------|
| <b>510(k) Number</b>                                  | This submission                    | K170490                       |
|                                                       |                                    |                               |
| Variable bed time (vBT)                               | Available                          | N/A                           |
| CaLM (Clear adaptive Low-noise Method Reconstruction) | Available                          | N/A                           |
| PET Respiratory Gating System (NKRS-001A)             | Available<br>-Workflow Improvement | Available                     |
| PET ECG gating (NHEG-001A)                            | Available                          | N/A                           |

#### 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, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18, NEMA XR-25 NEMA XR-25, NEMA XR-26 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.

Bench testing utilizing phantoms were conducted and it was determined that use of CaLM Reconstruction resulted in images with reduced noise while preserving detail and contrast. Representative clinical images were acquired to demonstrate that the subject device is capable of obtaining multi-phase, PET ECG gated data and that the new feature performs as intended.

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.

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.

## **18. CONCLUSION**

**Celesteion, PCA-9000A/3, V6.5**, 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.