December 23, 2024

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

Re: K242403
Trade/Device Name: Aquilion ONE (TSX-308A/3) V1.5
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: November 21, 2024
Received: November 22, 2024

Dear Orlando Tadeo Jr:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242403

Device Name

Aquilion ONE (TSX-308A/3) V1.5

Indications for Use *(Describe)*

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, pancreas, etc. The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

AiCE is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, cardiac, extremities, head, and inner ear applications.

The spectral imaging system allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid KV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies.
When used by a qualified physician, a potential application is to determine the course of treatment.

PIQE* is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac, abdomen and pelvis, and lung applications, in comparison to FBP and hybrid iterative reconstruction.

CLEAR Motion is a Deep Learning Reconstruction (DLR) method designed to reduce motion artifacts. A Deep Convolutional Neural Network (DCNN) is used to estimate the patient's motion. This information is used in the reconstruction process to obtain lung images with less motion artifacts.

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.

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510(k) SUMMARY

1. SUBMITTER'S NAME:

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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:

August 12, 2024

5. TRADE NAME(S):

Aquilion ONE (TSX-308A/3) V1.5

6. COMMON NAME:

Computed Tomography X-ray System

7. DEVICE CLASSIFICATION:

a) Classification Name: Computed Tomography X-ray system
b) Regulation Number: 21 CFR §892.1750
c) Regulatory Class: Class II

8. PRODUCT CODE:

JAK

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
Primary Predicate Device Aquilion ONE (TSX-308A/3) V1.4 with PIQE Reconstruction System	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K232835	April 2, 2024
Reference Predicate Device Aquilion ONE (TSX-306A/3) V10.12 with Spectral Imaging System	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K213504	June 16, 2022

11. REASON FOR SUBMISSION:

Modification of existing medical device

12. DEVICE DESCRIPTION:

Aquilion ONE (TSX-308A/3) V1.5 is a whole body multi-slice helical CT scanner, consisting of a gantry, couch and a console used for data processing and display. This device captures cross sectional volume data sets used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician. This system is based upon the technology and materials of previously marketed Canon CT systems.

13. INDICATIONS FOR USE:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, pancreas, etc. The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

AiCE is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, cardiac, extremities, head, and inner ear applications.

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PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac, abdomen and pelvis, and lung applications, in comparison to FBP and hybrid iterative reconstruction.

CLEAR Motion is a Deep Learning Reconstruction (DLR) method designed to reduce motion artifacts. A Deep Convolutional Neural Network (DCNN) is used to estimate the patient's motion. This information is used in the reconstruction process to obtain lung images with less motion artifacts.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE (TSX-308A/3) V1.5** is substantially equivalent to Aquilion ONE (TSX-308A/3) V1.4 with PIQE Reconstruction System, which received premarket clearance under K232835, and is marketed by Canon Medical Systems USA. The intended use of the **Aquilion ONE** is the same as that of the predicate device. A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	**Predicate Device**
Device Name, Model Number	**Aquilion ONE (TSX-308A/3) V1.5**	**Aquilion ONE (TSX-308A/3) V1.4 with PIQE Reconstruction System**
510(k) Number	**This submission**	**K232835**
PIQE Reconstruction System (CRRS-001A)	Available	Available
▪ Scan Regions	▪ Cardiac, *Lung*, Abdomen and pelvis (Body)	▪ Cardiac, Abdomen and pelvis (Body)
▪ Scan Type	▪ Volume scan, Dynamic volume scan, Helical scan	▪ Volume scan, Dynamic volume scan, Helical scan
3D Landmark Scan	Available X-ray tube voltage: 120kV	Available X-ray tube voltage: 120/135kV
Spectral Imaging System (CSDE-004A)	Option: BODY, LUNG, BONE and *CARDIAC (Cardiac previously cleared under K213504)*	Option: BODY, LUNG and BONE
Motion Correction		
Advanced Patient Motion Correction (APMC)	Available	Available
CLEAR Motion (CSCM-001A)	*Available*	Not Available
Connect Assistance (COCA-001A)	*Available* *(Previously cleared under K213504)*	Not Available
Area Finder (CGAP-003A)	*Available* *(Previously cleared under K213504)*	Not Available

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, IEC81001-5-1, IEC62366-1, NEMA XR-25, NEMA XR-26 and NEMA XR-29. 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.

Performance Testing - Bench

Image Quality Evaluations

CT image quality assessments were performed, utilizing phantoms, to evaluate PIQE Lung Image Quality, PIQE Body Image Quality and Spectral Cardiac Image Quality of the TSX-308A (Aquilion ONE) system relative to the predicate device, TSX-306A (Aquilion Prism) with regard to Contrast-to-Noise Ratios, CT Number Accuracy, Uniformity, Slice Sensitivity Profile, Modulation Transfer Function, Standard Deviation of Noise, Noise Power Spectra, and Low Contrast Detectability. It was concluded that the subject device demonstrated equivalent or improved performance, compared to the predicate device, as demonstrated by the results of the above testing.

CLEAR Motion Evaluations

Performance tests were conducted to evaluate the performance CLEAR Motion, utilizing phantoms and clinical images. These studies included comparing clinical lung images, a water phantom and a thoracic dynamic phantom (evaluated at 12 BPM), reconstructed with AIDR3D, AiCE and/or FBP with and without CLEAR Motion applied. Conclusions from these studies demonstrated that CLEAR Motion performed as intended, in that motion artifacts were significantly reduced and CT Numbers were maintained, compared to standard reconstructed images in which CLEAR Motion was not applied.

Performance Testing – Clinical Images

Representative body, cardiac, chest, head, and extremity diagnostic images, reviewed by American Board-Certified Radiologists, were obtained using the subject device and it was confirmed that the reconstructed images using the subject device were of diagnostic quality.

A summary of the risk analysis and verification/validation testing conducted through bench testing is included in this submission which demonstrates that the requirements for the system have been met.

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 **Aquilion ONE (TSX-308A/3) V1.5** 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.