March 7, 2023

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

Re: K223726
Trade/Device Name: Aquilion Precision (TSX-304A/4) V10.14 with AiCE
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 14, 2023
Received: February 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223726

Device Name

Aquilion Precision (TSX-304A/4) V10.14 with AiCE

Indications for Use *(Describe)*

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head. The Aquilion Precision has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. SUBMITTER'S NAME:

Fumiaki Teshima
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:

November 29, 2022

5. TRADE NAME(S):

Aquilion Precision (TSX-304A/4) V10.14 with AiCE

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
Aquilion Precision (TSX-304A/4) V10.10 with AiCE	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K220986	September 12, 2022

11. REASON FOR SUBMISSION:

Modification of existing medical device

12. DEVICE DESCRIPTION:

Aquilion Precision (TSX-304A/4) V10.14 with AiCE is an ultra-high resolution whole body multi-slice helical CT scanner, consisting of a gantry, couch and a console used for data processing and display. Aquilion Precision incorporates a 160-row, 0.25 mm detector, a 5.7- MHU large-capacity tube, and 0.35 s scanning, enabling wide-range scanning with short scan times to capture cross sectional volume data sets used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician. In addition, the subject device incorporates the latest reconstruction technology, FIRST, intended to reduce exposure dose while maintaining and/or improving image quality as well as, AiCE (Advanced intelligent Clear-IQ Engine), intended to reduce image noise and improve image quality by utilizing Deep Convolutional Neural Network methods to 1024x1024 HR/SHR images. These methods can more fully explore the statistical properties of the signal and noise. By learning to differentiate structure from noise, the algorithm produces fast, high quality CT reconstruction.

13. INDICATIONS FOR USE:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion Precision has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, 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.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Precision (TSX-304A/4) V10.14 with AiCE** is substantially equivalent to **Aquilion Precision (TSX-304A/4) V10.10 with AiCE**, which received premarket clearance under K220986, and is marketed by Canon Medical Systems USA. The intended use of the Aquilion Precision is the same as that of the predicate device. The **Aquilion Precision (TSX-304A/4) V10.14 with AiCE** includes changes made to the predicate device that expand the use of AiCE to extremities, head, and inner ear applications. A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion Precision (TSX-304A/4) V10.14 with AiCE**	**Aquilion Precision (TSX-304A/4) V10.10 with AiCE**	
510(k) Number	**This submission**	**K220986**	
AiCE Modifications			
• Scan Regions	Abdomen and Pelvis/ Chest/Cardiac/ Extremities*/Brain*/ Inner Ear*	Abdomen and Pelvis/ Chest/Cardiac	*Added
• Magnified reconstruction - Available magnification Size (D-FOV)	BODY / BODY SHARP: Min. 100 mm LUNG: Min. 100 mm CARDIAC: Min. 70 mm BONE / INNER EAR: Min. 50 mm BRAIN CTA: Min. 100 mm Max. 500 mm	BODY / BODY SHARP: Min. 100 mm LUNG: Min. 100 mm CARDIAC: Min. 70 mm Max. 500 mm	The minimum FOV differs depending on the anatomical region.
• Reconstruction processing system [AiCE] (CSAL-002A)	Option [Reconstruction Processing Unit required]	N/A [AiCE implemented with Reconstruction Processing Unit (CCRS-003B)]	
• Applicable anatomical regions	• BODY and BODY SHARP (For Abdomen and Pelvis) • LUNG (For Chest) • CARDIAC (For Cardiac) • BONE (For extremities)* • BRAIN CTA (For brain)* • INNER EAR (For inner ear)*	• BODY and BODY SHARP (For Abdomen and Pelvis) • LUNG (For Chest) • CARDIAC (For Cardiac)	*Added

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 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.

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

CT image quality metrics were performed, utilizing phantoms, to assess Contrast-to-Noise Ratios (CNR), CT Number Accuracy, Uniformity, Slice Sensitivity Profile (SSPz), Modulation Transfer Function (MTF)-Wire, Modulation Transfer Function (MTF)-Edge, Standard Deviation of Noise (SD), Noise Power Spectra (NPS), Low Contrast Detectability (LCD) and Pediatric conditions. AiCE is substantially equivalent to the predicate device as demonstrated by the results of the above testing.

Quantitative Spatial Resolution Improvement

A spatial resolution comparison study was conducted to support a high contrast spatial resolution improvement claim of 5.37 lp/cm improvement for Bone in HR mode, 7.50 lp/cm improvement for Inner Ear in HR mode, and 11.31 lp/cm improvement for Brain CTA in HR mode, all compared to hybrid iterative reconstruction at 10% MTF and at the same dose.

Performance Testing – Clinical Images

Representative Abdomen Bone, Brain CTA, and Inner Ear images, reviewed by an American Board Certified Radiologist, 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 and clinical testing is included in this submission which demonstrates that the requirements for the system have been met.

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 included in this submission. This documentation includes justification for the Moderate Level of Concern determination as well as testing which demonstrates that the verification and validation requirements for the modifications described above have been met.

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.

17. CONCLUSION

The **Aquilion Precision (TSX-304A/4) V10.14 with AiCE** 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 safe and effective for its intended use.