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

July 5, 2019

Re: K182901
Trade/Device Name: Aquilion Precision (TSX-304A/1 and /2) V8.8 with AiCE
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: July 11, 2019
Received: July 12, 2019

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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182901

Device Name

Aquilion Precision (TSX-304A/1 and /2) V8.8 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 3.0 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 and pelvis 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.

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510(k) SUMMARY K182901

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

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, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

5. Date Prepared:
June 11, 2019

6. TRADE NAME(S):
Aquilion Precision (TSX-304A/1 and /2) V8.8 with AiCE

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

8. DEVICE CLASSIFICATION (Regulatory Class, CFR Reference, Name):
Class II (per 21 CFR 892.1750, Computed Tomography X-ray System)

9. PRODUCT CODE / DESCRIPTION:
JAK / Computed Tomography X-Ray 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
Aquilion Precision (TSX-304A/2) V8.6	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K173468	02/23/2018

12. REASON FOR SUBMISSION:

Modification of existing medical device

13. DEVICE DESCRIPTION:

Aquilion Precision (TSX-304A/1 and /2) V8.8 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, 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.

14. 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 3.0 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 and pelvis applications.

15. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Precision (TSX-304A/1 and /2) V8.8 with AiCE**, is substantially equivalent to the Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0, which received premarket clearance under K173468 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 changes made to the subject device include the addition of AiCE (Advanced intelligent Clear-IQ Engine), a reconstruction algorithm that utilizes Deep Convolutional Neural Network methods to reduce image noise and improve image quality. A comparison of the technological characteristics between the subject and the predicate device is included below.

Item	Aquilion Precision (TSX-304A/1 and 2) V8.8 with AiCE	Aquilion Precision (TSX-304A/2) V8.6 K173468
Anatomical Region	Whole Body (FBP, AIDR 3D, FIRST) Abdomen and pelvis (AiCE)	Whole Body (FBP, AIDR 3D, FIRST)
Noise Reduction Processing	AIDR 3D AIDR 3D Enhanced AiCE	AIDR 3D AIDR 3D Enhanced
Central processing unit memory size	128 Gbytes or more	256 Gbytes or more
Patient couch - Frame slide stroke	310 mm	330 mm
Handy Snap* (CAXS-001A)	Optional	N/A
Dual energy system* package (CSDP-001A)	Optional	N/A

*Feature previously cleared under K141741. No changes made for implementation into the subject device.

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-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.

17. TESTING

Risk analysis and verification/validation testing conducted through bench testing demonstrate that the established specifications for the device have been met.

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 (SSP), 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 water phantom. AiCE is substantially equivalent to the predicate device as demonstrated by the results of the above testing.

Low Contrast Detectability, Noise Reduction, Dose Neutrality

AiCE demonstrated 13% improved low contrast detectability and 42% noise reduction for super-high resolution body at the same dose compared to AIDR 3D. Additionally, it was demonstrated that there is dose neutrality between super-high resolution mode with AiCE and normal resolution mode with AIDR as well as superior LCD performance for super-high resolution body at the same dose for AiCE vs AIDR 3D.

Spatial Resolution

A spatial resolution comparison study was conducted to support a high contrast spatial resolution improvement claim of 8.8 lp/cm at 10% of the MTF for AiCE relative to AIDR 3D Standard for abdomen/body.

Representative abdomen/pelvis diagnostic images, reviewed by an American Board Certified Radiologist, were obtained using the subject device and it was confirmed that the AiCE reconstructed images were of diagnostic quality.

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.

18. CONCLUSION

The **Aquilion Precision (TSX-304A/1 and /2) V8.8 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.