September 10, 2021

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

Re: K211828
Trade/Device Name: Aquilion Exceed LB (TSX-202A/3) V10.9 with AiCE-i
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 20, 2021
Received: August 23, 2021

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 (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)*
K211828

Device Name

Aquilion Exceed LB (TSX-202A/3) Vl0.9 with AiCE-i

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 Exceed LB 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.

AiCE (Advanced Intelligent Clear-IQ Engine) is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, 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

K211828

1. SUBMITTER'S NAME:
Canon Medical Systems Corporation
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, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

5. DATE PREPARED:
June 11, 2021

6. TRADE NAME(S):
Aquilion Exceed LB (TSX-202A/3) V10.9 with AiCE-i

7. COMMON NAME:
Computed Tomography X-ray system

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

9. PRODUCT CODE:
JAK

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
Primary: Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K203042	12/10/2020
Reference: Dual Energy System Package, CSDP-001A	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K132813	02/06/2014

12. REASON FOR SUBMISSION:

Modification of an existing device to expand the clinical use of AiCE to cardiac applications

13. DEVICE DESCRIPTION:

Aquilion Exceed LB (TSX-202A/3) V10.9 with AiCE-i (Advanced intelligent Clear-IQ Engine-integrated) 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.

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 Exceed LB 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.

AiCE (Advanced Intelligent Clear-IQ Engine) 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.

15. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Exceed LB (TSX-202A/3) V10.9 with AiCE-i** is substantially equivalent to **Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i**, which received premarket clearance under K203042, and is marketed by Canon Medical Systems USA. The changes made to the subject device include expansion of the clinical use of AiCE to include cardiac applications (previously cleared under K192832), introduction of Dual Energy imaging (originally cleared under K132813) including new features and implementation of SUREStart and Single Energy Metal Artifact Reduction (SEMAR) to the XL scan field. A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	Primary Predicate Device
Device Name, Model Number	**Aquilion Exceed LB (TSX-202A/3) V10.9 with AiCE-i**	**Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i**
510(k) Number	**This submission**	**K203042**
SURE Start	12 measurements/s Applicable to the XL scan field.	12 measurements/s

	Subject Device	Primary Predicate Device
Device Name, Model Number	**Aquilion Exceed LB (TSX-202A/3) V10.9 with AiCE-i**	**Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i**
510(k) Number	**This submission**	**K203042**
Parameter editing	Up to 7 pairs of Volume and Multiview reconstructions can be prescribed.	Up to 3 pairs of Volume and Multiview reconstructions can be prescribed.
Metal Artifact Reduction	Single Energy Metal Artifact Reduction (SEMAR) Applicable to the XL scan field.	Single Energy Metal Artifact Reduction (SEMAR)
Noise Reduction Processing	Quantum Denoising Software (QDS) Adaptive Integrative Dose Reduction 3D (AIDR 3D), AIDR 3D Enhanced AiCE (Advanced Intelligent Clear - IQ Engine) • Abdomen and Pelvis • Chest • Extremities • Brain • Inner ear • Cardiac	Quantum Denoising Software (QDS) Adaptive Integrative Dose Reduction 3D (AIDR 3D), AIDR 3D Enhanced AiCE (Advanced Intelligent Clear - IQ Engine) • Abdomen and Pelvis • Chest • Extremities • Brain • Inner ear
Dual energy system package (CSDP-001A)	Available New Features: Generation of Electron Density Map Generation of Effective Atomic Number Map	N/A
Extended field of view (CSTC-005A)	Available Can be set with SEMAR	Available
Magnified reconstruction - Available magnification Size (D-FOV)	BODY / BODY SHARP: Min. 100 mm LUNG: Min. 100 mm BONE: Min. 50 mm INNER EAR: Min. 50 mm BRAIN LCD / CTA: Min. 100 mm CARDIAC: Min. 70 mm Max. 700 (900*) mm *Option	BODY / BODY SHARP: Min. 100 mm LUNG: Min. 100 mm BONE: Min. 50 mm INNER EAR: Min. 50 mm BRAIN LCD / CTA: Min. 100 mm Max. 700 (900*) mm *Option

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, 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]

17. 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 (SSP), Modulation Transfer Function (MTF), Standard Deviation of Noise (SD), Noise Power Spectra (NPS) and Low Contrast Detectability (LCD). It was concluded that the Aquilion Exceed LB system demonstrated substantially equivalent or improved performance relative to the predicate device as demonstrated by the results of the above testing.

Dual Energy – Electron Density

Phantom studies were conducted using the CBCT Electron Density Phantom and the results demonstrated that the mean and SD error between the measured and true Electron Density values fall within the established criteria and that precise electron density accuracy is maintained throughout the field of view with monoenergetic images.

Dual Energy – Effective Atomic Number Map

A phantom study was conducted using the Catphan 700 phantom and the results demonstrated that the mean and SD error between the measured and true Effective atomic number images fall within the established accuracy criteria.

Dual Energy – CT Number Accuracy

A phantom study was conducted using the Catphan 600 phantom and the results demonstrated that precise CT number accuracy is maintained throughout the field of view on 70keV monoenergetic images.

Representative cardiac 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 Exceed LB (TSX-202A/3) V10.9 with AiCE-i** 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.