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

January 12, 2021

Re: K201836
Trade/Device Name: Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: December 9, 2020
Received: December 10, 2020

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)*

K201836

Device Name

Aquilion Lightning (TSX-036A/7) V10.2 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 Lightning 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.

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.

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K201836

510(k) SUMMARY

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 30, 2020

6. **TRADE NAME(S):**
   Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i

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

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

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, Computed Tomography

10. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Aquilion Lightning, TSX-036A/1, V8.4 (*Primary Predicate Device*)	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K170019	February 2, 2017
Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i (*Reference Device*)	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K192832	February 21, 2020

11. REASON FOR SUBMISSION:

Modification of a cleared device

12. DEVICE DESCRIPTION:

Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i. The **Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i** is an 80-row CT system that is a whole body, multi-slice helical CT scanner, consisting of a gantry, couch and 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. In addition, the subject device incorporates the latest reconstruction technology, **AiCE-i (Advanced intelligent Clear-IQ Engine - integrated)**, intended to reduce image noise and improve image quality by utilizing Deep Convolutional Neural Network (DCNN) methods. This reconstruction algorithm is predicated on AiCE reconstruction algorithm previously 510(k) cleared per K192832 on the Canon CT scanner **Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i**, which serves as a reference predicate for this submission. The DCNN 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 for every patient.

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 Lightning 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.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i**, is substantially equivalent to the **Aquilion Lightning (TSX-036A/1) V8.4**, which received premarket clearance under K170019 and is marketed by Canon Medical Systems USA. The intended use of the **Aquilion Lightning** is the same as that of the predicate device. The changes made to the subject device include the addition of AiCE-i (Advanced intelligent Clear-IQ Engine-integrated), a reconstruction algorithm that utilizes Deep Convolutional Neural Network methods to reduce image noise and improve image quality, previously cleared under K192832. A comparison of the technological characteristics between the subject and the predicate device is included below.

Item	**Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i**	**Aquilion Lightning (TSX-036A/1) V8.4**
510(k) Clearance Number	N/A	K170019
Anatomical Region	AIDR 3D (Whole Body) AiCE (Abdomen and Pelvis, Chest, Cardiac, Extremities, Brain, Inner ear)	AIDR 3D (Whole Body)
Noise Reduction Processing	AIDR 3D AIDR 3D Enhanced Quantum Denoising Smoothing (QDS) AiCE	AIDR 3D AIDR 3D Enhanced Quantum Denoising Smoothing (QDS)
Processing capability	Console CKCN-020C Reconstruction processing system (AiCE-i: CSAL-001A)	Console CKCN-020C Reconstruction processing system (N/A)
Image Quality Claim	- Improved Quantitative high contrast Spatial Resolution over AIDR 3D with reduced noise - Improved Quantitative Dose Reduction over FBP - Better Low-contrast Detectability than AIDR 3D for abdomen at the same dose -Noise appearance/texture similar to filtered backprojection	-N/A -N/A -N/A -N/A
Operating System	Microsoft Windows 10	Microsoft Windows 10

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, IEC60601-1-9, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, 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.

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, Standard Deviation of Noise (SD), Noise Power Spectra (NPS), Low Contrast Detectability (LCD). It was concluded that the AiCE-i images are substantially equivalent to the predicate device as demonstrated by the results of the above testing.

Quantitative Spatial Resolution

A phantom study was conducted to compare spatial resolution performance between AiCE, filtered backprojection and AIDR 3D. It was determined that there is double the high contrast spatial resolution versus AIDR 3D for body (AiCE Body Sharp).

Quantitative Body LCD, Noise Improvement and Dose Reduction

A dose reduction study was conducted using AiCE and based on the results, a dose reduction claim of up to 82.9%, relative to FBP, is supported as well as 15% improved low contrast detectability and noise reduction of 29% at the same dose for body compared to AIDR 3D.

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 as part of 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.

It was determined that representative clinical images were not necessary to demonstrate substantial equivalence of the subject device.

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.

17. CONCLUSION

The **Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i** is substantially equivalent to **Aquilion Lightning (TSX-036A/1) V8.4**, which was cleared via Pre-Market Notification 510(k), K170019. The

Aquilion Lightning (TSX-036A/7) V10.2 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.