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

September 6, 2019

Re: K192188
Trade/Device Name: Aquilion ONE (TSX-306A/3) V10.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 12, 2019
Received: August 13, 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)*

K192188

Device Name

Aquilion ONE (TSX-306A/3) V10.0

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.

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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K192188

510(k) SUMMARY

1. SUBMITTER'S NAME:
Canon Medical Systems Corporation
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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:
August 30, 2019

6. TRADE NAME(S):
Aquilion ONE (TSX-306A/3) V10.0

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 / Computed Tomography X-Ray System

10. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Aquilion ONE (TSX-305A/6) V8.9 with AiCE	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K183046	06/12/2019

11. REASON FOR SUBMISSION:

Modification of existing medical device

12. DEVICE DESCRIPTION:

Aquilion ONE (TSX-306A/3) V10.0 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.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE (TSX-306A/3) V10.0** is substantially equivalent to **Aquilion ONE (TSX-305A/6) V8.9 with AiCE**, which received premarket clearance under K183046, and is marketed by Canon Medical Systems USA. The intended use and the indications for use of the Aquilion ONE is the same as that of the predicate device. The **Aquilion ONE (TSX-306A/3) V10.0** includes changes made to the predicate device including modifications made to the X-ray generator, gantry and detector in order to support rapid kV switching scans, the Windows operating system version is updated to Windows 10 from Windows 7, and to update the SUREFluoro operating panel. 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 ONE, TSX-306A/3**	**Aquilion ONE (TSX-305A/6) V8.9 with AiCE**	
510(k) Number	**This submission**	**K183046**	
X-ray generator (HFG)	CXXG-018A	CXXG-013A	Modifications to support rapid kV switching -X-ray high-voltage generator upgrade kit, Model CXGS-020A, also available to upgrade existing TSX-305A systems. -CXXG-013A with CXGS-020A is equivalent to the high voltage generator used in TSX-306A, Model CXXG-018A.

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion ONE, TSX-306A/3**	**Aquilion ONE (TSX-305A/6) V8.9 with AiCE**	
510(k) Number	**This submission**	**K183046**	
Gantry	Model CGGT-039A	CGGT-036A	Modifications to support rapid kV switching and acquisition view synchronization capabilities
- Exterior covers	Surface and paint with gloss coating	Surface and paint	Gloss coating is added
Detector model	CDAS-052A/6A	CDAS-052A/5A	Modifications to support the rapid kV switching and kV view synchronization. No change in the hardware.
Type of X-ray tube	CXB-750F	CXB-750F	Improvement for stabilization during electrical discharge
Rear operating panel kit (CAGP-003A)	Option (Paint with gloss coating)	Option (Paint)	Gloss coating is added
System Software Version	V10.0	V8.9	Change
Console operating system	Windows 10	Windows 7	Upgrade
SURE Fluoro	Option TSXF-004A	Option TSXF-003I	Change Updated operating panel installed on the patient couch
AiCE	N/A	Option	Change
FIRST	N/A	Option	Change

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, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, 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. An image quality evaluation using phantom-based tests was performed to compare the **Aquilion ONE (TSX-306A/3) V10.0** and the predicate device. Results of the testing demonstrated substantial equivalence of image

quality between the systems, with regard to standard deviation of noise (CT number accuracy, image SD, spatial resolution (high contrast detectability) and density resolution (low contrast detectability)). As a result of the phantom-based tests, it was determined that clinical data was not necessary to demonstrate substantial equivalence between the **Aquilion ONE (TSX-306A/3) V10.0** and the predicate device.

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.

17. CONCLUSION:

The **Aquilion ONE (TSX-306A/3) V10.0** 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.