Canon Medical Systems Corporation
% Mr. Paul Biggins
Senior Director Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

June 5, 2019

Re: K190505
Trade/Device Name: Low Dose CT Lung Cancer Screening Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 17, 2019
Received: May 20, 2019

Dear Mr. Biggins:

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)*

K190505

Device Name

Low Dose CT Lung Cancer Screening Option

Indications for Use *(Describe)*

The Low Dose CT Lung Cancer Screening Option for Canon/Toshiba CT systems is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols that have been approved and published by a governmental body, a professional medical society and/or Canon.

Information from professional societies related to lung cancer screening can be found, but is not limited to:
American College of Radiology® (ACR) – resources and technical specification; accreditation
American Association of Physicists in Medicine (AAPM) – Lung Cancer Screening Protocols; radiation management.

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."

K190505

510(k) SUMMARY

1. SUBMITTER'S NAME:

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara, Japan 324-8550

2. OFFICIAL CORRESPONDENT:
Naofumi Watanabe

3. ESTABLISHMENT REGISTRATION:
9614698

4. CONTACT PERSON:
Paul Biggins
Senior Director Regulatory Affairs/U.S. Agent
Canon Medical Systems USA, Inc.
2441 Michelle Drive, Tustin, CA 92780
714-669-7808

5. DATE PREPARED:
May 31, 2019

6. TRADE NAME(S):
Low Dose CT Lung Cancer Screening Option

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

8. DEVICE CLASSIFICATION:
Class II (per 21 CFR 892.1750)

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

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	510(k) Number	Clearance Date
Aquilion RXL	Toshiba America Medical Systems	K121553	July 26, 2012

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

The low dose lung cancer screening option is an indication being added to the following existing, previously FDA-cleared scanners:

510(K) NUMBER	**PRODUCT Family – Aquilion TSX-101**
K033418	AQUILION MULTISLICE CT SCANNERS (TSX-101A/A AND TSX-101A/C)
K051833	AQUILION 64 SP CT SCANNER; AQUILION 32 SP CT SCANNER (TSX-101A/H, TSX-101A/I)
K080211	AQUILION 32/64 SP CT SYSTEM (TSX-101A/H, TSX-101A/I)
K112989	AQUILION CXL (TSX-101A/Q)
K121553	AQUILION RXL (TSX-101A/R)
510(K) NUMBER	**PRODUCT Family – Lightning TSX-035/TSX-036**
K151833	Aquilion Lightning (TSX-035A/2 V7.0)
K153263	Aquilion Lightning (TSX-035A/4 and /5 V7.0)
K170019	Aquilion Lightning (TSX-036A/1 V8.4)
510(K) NUMBER	**PRODUCT Family – Aquilion ONE TSX-301/TSX-305**
K063189	AQUILION ONE CT SYSTEM (TSX-301A)
K072606	AQUILION ONE CT SYSTEM (TSX-301A/2)
K083282	AQUILION ONE CT SYSTEM (TSX-301B)
K093891	AQUILION ONE VERSION 4.6 W/DUAL ENERGY (TSX-301A/2)
K113466	AQUILION ONE (TSX-301A)
K120546	AQUILION ONE PREMIUM (TSX-301B)
K122109	AQUILION ONE VISION V4.90 (TSX-301C)
K132222	AQUILION ONE VISION V6.0 (TSX-301C)
K133497	AQUILION ONE VISION (TSX-301C)
K142465	Aquilion ONE Vision v7.0 (TSX-301C)
K160587	Aquilion ONE GENESIS V7.3 (TSX-305A/3)
K161009	Aquilion ONE Vision with FIRST 2.0 V7.4 (TSX-301C)
K170177	Aquilion ONE GENESIS V8.3 with FIRST 2.1 (TSX-305A/3)
510(K) NUMBER	**PRODUCT Family – Prime TSX302/TSX-303**
K110066	AQUILION PRIME (TSX-302A)
K120710	AQUILION PRIME (TSX-302A)
K130645	AQUILION PRIME V5.00 (TSX-303A)
K141741	AQUILION PRIME V6.00 (TSX-303A)
K172188	Aquilion Prime SP v8.4 (TSX-303B/1)

No functional, performance, feature, or design changes are being made to the devices that will be indicated for low dose lung cancer screening. The devices already include low dose lung screening protocols, intended for use in the review of thoracic CT images within the established inclusion criteria of programs/protocols that have been approved and published by either a governmental body or professional medical society: Please refer to clinical literature that includes the results of the National Lung Screening Trial (*N Engl J Med* 2011; **365**:395-409) and subsequent literature, for further information.

14. INDICATIONS FOR USE:

The Low Dose CT Lung Cancer Screening Option for Canon/Toshiba CT systems is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols that have been approved and published by a governmental body, a professional medical society and/or Canon.

Information from professional societies related to lung cancer screening can be found, but is not limited to:

American College of Radiology® (ACR) – resources and technical specification; accreditation

American Association of Physicists in Medicine (AAPM) – Lung Cancer Screening Protocols; radiation management.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (*N Engl J Med* 2011; **365**:395-409) and subsequent literature, for further information.

15. SUBSTANTIAL EQUIVALENCE:

Following FDA recommendations during the October 8, 2014 meeting with MITA, Toshiba followed the November 1998 General vs. Specific Guidance document to help establish that the indication for the Low Dose CT Lung Cancer Screening Option does not constitute a new intended use for the device, and that the Option could therefore be further evaluated for substantial equivalence, as per the flowchart found in the July 28, 2014 "Evaluating Substantial Equivalence in Premarket Notifications" guidance document.

The NLST made use of the Aquilion 16 scanner. However, because the Aquilion 16 is out of production, and also because FDA has been moving toward restricting predicate devices to devices cleared within the previous ten years, after consulting FDA Canon Medical selected the Aquilion RXL as the predicate device. The Aquilion RXL is the successor 16-row to the Aquilion 16, and therefore offers a higher, more modern standard of image quality to compare against.

Canon Medical grouped our CT systems into three different platforms/families based on their technological characteristics: The Aquilion 16/32/64/RXL, PRIME/PRIME SP, ONE/ViSION/Genesis, and Lightning platforms. We have provided bench data from a representative scanner in each family. The NLST data were acquired on scanners from the Aquilion 16/64/RXL family. We therefore selected the RXL as the predicate.

For one device in each of the families, Canon Medical provided bench testing data to demonstrate performance that was substantially equivalent to the NLST predicate.

To demonstrate substantial equivalence of the new LDCT LCS option to the predicate device, Canon Medical is providing bench testing data. The bench testing measured traditional image quality metrics on standard phantoms, and compared to the image quality results from the predicate scanner, which is a contemporary member of the family of Toshiba scanners used in the NLST, with similar technological characteristics as, and performance equivalent to the NLST scanner.

To demonstrate substantial equivalence of other CT systems to the predicate device, Canon Medical compared objective image quality bench testing for each subject device to that of the predicate device.

Canon Medical has identified the following bench tests as relevant to assessing a CT scanner's low-dose lung-cancer screening performance:

Image Quality Metric	**Relevance to low-dose lung cancer screening**
Modulation Transfer Function (MTF)	Quantifies the in-plane spatial resolution performance of the system.
Axial Slice Thickness	Quantifies the longitudinal resolution performance of the system.
Contrast to Noise Ratio (CNR)	Quantifies the signal strength relative to the standard deviation of noise.
CT number uniformity	Quantifies the stability of the Hounsfield Unit for water across the FOV.
Noise Performance (Noise Power Spectrum)	Quantifies the noise properties of the system.

To demonstrate substantial equivalence of other CT systems to the predicate device, Canon Medical compared objective image quality bench testing for each subject device to that of the predicate 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 IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, IEC60601-1-6, IEC60601-2-28, IEC60601-2-32, 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

Canon Medical grouped our CT systems into three different platforms/families based on their technological characteristics: The Aquilion 16/32/64/RXL, PRIME/PRIME SP, ONE/ViSION/Genesis, and Lightning. We have provided bench data from a representative scanner in each family. The NLST data were acquired on scanners from the Aquilion 16/64/RXL family. We therefore selected the RXL as the predicate.

For one device in each of the families, Canon Medical provided bench testing data to demonstrate performance that was substantially equivalent to the NLST predicate. We have additionally provided clinical literature to demonstrate that newer technologies, such as iterative reconstruction, have not negatively affected the devices' safety and effectiveness.

18. CONCLUSION

Canon Medical has demonstrated, via the criteria in the "General vs. Specific Intended Use" guidance document, that the lung cancer screening indication does not change the intended use of the device. Because the subject and predicate devices are all FDA-cleared for general CT imaging, of which lung cancer screening is a specific application, the different technological characteristics do not raise different questions of safety and effectiveness than the predicate device used in the NLST. To supplement the NLST data, Canon Medical has identified bench data relating to device performance for low-dose lung screening, and provided data demonstrating substantial equivalence. Canon Medical has also identified clinical studies using newer devices than the NLST that demonstrate that the new technological characteristics of post-NLST devices have not negatively impacted their safety and effectiveness.

Canon would also respectfully present to FDA that the ACR currently has over 4,000 sites/CT systems that are accredited with respect to the ACR guidelines. Based upon the latest IMV research that the installed base of CT scanners for Canon/Toshiba is approximately 17%. Extrapolation of the ACR database would then infer that over 680 Canon/Toshiba CT scanners are currently accredited for lung screening and there have been no reports of adverse events related to this clinical practice.

CT systems that include the lung cancer screening option remain in compliance with the applicable US and international safety and performance standards such as United States Code of Federal Regulations Title 21, Subchapter J – Radiological Health, NEMA, DICOM, and IEC standards.