September 14, 2018

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

Re: K182223
Trade/Device Name: Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 15, 2018
Received: August 16, 2018

Dear Orlando 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K182223

Device Name

Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A

Indications for Use *(Describe)*

Optional movable gantry base unit for use with an Aquilion ONE (TSX-305A) system to support longitudinal movement and allow acquisition of images in the z-direction (z-axis).

Note: When installed with the movable gantry base unit, Aquilion ONE can be used with the INFX-8000C system in the same room.

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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CANON MEDICAL SYSTEMS USA, INC.

Made For life

510(k) SUMMARY

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

2. **OFFICIAL CORRESPONDENT**
   Naofumi Watanabe

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
   otadeo@us.medical.canon
   (714) 669-7459

5. **Date Prepared:**
   August 15, 2018

6. **TRADE NAME(S):**
   Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A

7. **COMMON NAME:**
   Computed Tomography X-Ray System

8. **DEVICE CLASSIFICATION:**
   Regulatory Class: II
   Regulation Number: 21 CFR 892.1750
   Regulation Name: Computed Tomography X-Ray System
   Product Code: JAK

9. **PERFORMANCE STANDARD:**
   This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

10. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT	Canon Medical Systems USA	21 CFR 892.1750	Computed Tomography System	JAK	K143223	January 12, 2015
Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1	Canon Medical Systems USA	21 CFR 892.1750	Computed Tomography System	JAK	K170177	June 30, 2017
Alphenix, INFX-8000C/B, V8.0	Canon Medical Systems USA	21 CFR 892.1650	Image-intensified fluoroscopic x-ray system	OWB	K181804	August 2, 2018

11. REASON FOR SUBMISSION:

Modification of a cleared device.

The purpose of this submission is to seek market clearance for Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A.

12. DEVICE DESCRIPTION:

The Infinix 4DCT is composed of the INFX-8000C interventional angiography system and the dynamic volume CT system, Aquilion ONE, TSX-305A/3. This combination enables patient access and efficient workflow for interventional procedures. Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A, is an optional kit intended to be used in conjunction with an Aquilion ONE / INFX-8000C based IVR-CT system. This device is attached to the Aquilion ONE CT gantry to support longitudinal movement and allow image acquisition in the z-direction (Z-axis), both axial and helical. When this option is installed, the standard CT patient couch is replaced with the patient handling system utilized by the interventional x-ray system, INFX-8000C. The Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A, will be used as part of an Aquilion ONE / INFX-8000C based IVR-CT system. Please note, the intended uses and technological characteristics of the Aquilion ONE CT System and the INFX-8000C Interventional X-Ray System remain the same. There have been no modifications made to the imaging chains in these FDA cleared devices and the base system software remains the same. Since both systems will be installed in the same room and to prevent interference during use, system interlocks have been incorporated into the systems.

Please note: The terms “Self-Propelled Scan Base”, “Moving Base” and “Movement Base” are used interchangeably throughout this submission. They all refer to the same unit.

13. INDICATIONS FOR USE:

Optional movable gantry base unit for use with an Aquilion ONE (TSX-305A) system to support longitudinal movement and allow acquisition of images in the z-direction (z-axis).

Note: When installed with the movable gantry base unit, Aquilion ONE can be used with the INFX-8000C system in the same room.

14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT, which received premarket clearance under K143223, marketed by Canon Medical Systems USA.

Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A, incorporates modifications to the cleared device in order for the self-propelled scan base unit to be connected to an Aquilion One CT gantry. This allows the CT system to acquire images in the z-direction (Z-axis) when a fixed catheterization table is used for patient support instead of a dedicated CT patient couch. The indications for use, method of operation including the imaging chain, base software and manufacturing process of the CT and Interventional XR systems remain unchanged from the cleared devices.

See below for a brief summary of changes from Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A:

Item	**Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A**	**CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT**	**Comments**
CT System	Aquilion ONE (K170177)	Aquilion PRIME (K141741)	Changed
X-Ray System	INFX-8000C (V8.2 Software) (K181804)	INFX-8000C (V6.01 Software) (K113052)	Changed
Gantry drive	Movement along rails laid on the floor	Movement along rails laid on the floor	Same
Cabling	Floor cabling	Floor cabling	Same
Digging depth of the floor	Approximately 130 mm	Approximately 152 mm	Reduced digging depth
Couch	Fixed catheterization table (INFX-8000C System)	Fixed catheterization table (INFX-8000C System)	Same
Scan direction	IN/OUT directions	IN/OUT directions	Same
Direction of Scanogram acquisition	IN/OUT directions	IN/OUT directions	Same
Gantry Tilt	Max. +/-28°	Max. +/-30°	Changed

Item	Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A	CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT	Comments
Scanoscopy speed	90 - 110 mm/s (Remote access Possible from the console except Table Up/Down operation)	100 mm/s	Changed
Scan field in the longitudinal direction	Scanoscopy: Adjustable from 200 mm to 1800 mm Helical scan: Max. 1800 mm/scan	Scanoscopy: Adjustable from 200 mm to 1390 mm Helical scan: Max. 1390 mm/scan	Changed

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 IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, IEC60601-1-6, IEC60601-1-9, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, IEC 60825, NEMA PS 3.1-3.18, NEMA XR-25 and NEMA XR-26. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

16. TESTING

This submission includes summary tables detailing the risk analysis and verification/validation testing conducted through bench testing which demonstrates that the requirements for the modifications made to the system have been met. Evaluation of the modified device included, but was not limited to, confirmation that base movement speed, stop position accuracy, scanogram and axial/helical scan functions, and interlocks including contact detection, emergency stop and slide running performed according to specifications.

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.

Additionally, testing of the modified system 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 Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A is substantially equivalent to the predicate device. The subject device function in a manner similar to and is intended for the same use as the predicate device, as described in the labeling. Based upon the bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.