August 28, 2025

4DMedical Limited
% Theresa Poole
Senior Director of Regulatory and Quality Affairs
Level 7/700 Swanston Street
CARLTON, VIC 3053
AUSTRALIA

Re: K251484
Trade/Device Name: CT:VQ
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: July 30, 2025
Received: July 31, 2025

Dear Theresa Poole:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251484

Device Name
CT:VQ

Indications for Use *(Describe)*
CT:VQ software is a non-invasive image post-processing technology, using CT lung images to provide clinical decision support for thoracic disease diagnosis and management in adult patients. It utilizes two non-contrast chest CT studies to quantify and visualize ventilation and perfusion.

Quantification and visualizations are provided as DICOM images. CT:VQ may be used when Radiologists, Pulmonologists, and/or Nuclear Medicine Physicians need a better understanding of a patient's lung function and/or respiratory condition.

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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510(k) Summary: CT:VQ

This 510(k) Summary of safety and effectiveness information is submitted as part of the Pre-Market Notification in accordance with the requirements of 21 CFR Part 807, Subpart E, Section 807.92.

1. Submitter Information

Submitter:	**4DMedical Limited** Level 7 700 Swanston Street Carlton, VIC 3053 Australia
Primary contact person:	Theresa Poole Email: tpoole@4dmedical.com Ph: + 1-603-724-5657
Secondary contact person:	Rachael Tenkaten Email: regulatory@4dmedical.com Ph: + 61 3 9545 5940

Date prepared:	May 13, 2025

2. Subject Device

510(k) number:	K251484
Name of Device:	CT:VQ
Manufacturer:	4DMedical Limited
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed Tomography X-ray System
Classification Class:	Class II
Product Code:	JAK

3. Legally Marketed Predicate Devices

Primary Predicate Device

510(k) number:	K232392
Name of Device:	CT Lung Ventilation Analysis Software
Manufacturer	4DMedical Limited
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed Tomography X-ray System
Classification Class:	Class II
Product Code:	JAK

Secondary Predicate Device

510(k) number:	K090504
Name of Device:	CSBP-001A; Body Organ Perfusion System
Manufacturer	Toshiba America Medical Systems, Inc.
Regulation Number:	21 CFR 892.1750
Regulation Name:	System, X-Ray, Tomography, Computed
Classification Class:	Class II
Product Code:	JAK

4. Device Description

CT:VQ is a Software as a Medical Device (SaMD) technology, which can be used in the analysis of a paired (inspiratory/expiratory) non-contrast Chest CT. It is designed to measure regional ventilation (V) and regional perfusion (Q) in the lungs.

The Device provides visualization and quantification to aid in the assessment of thoracic diseases. These regional measures are derived from the lung tissue displacement, the lung volume change, and the Hounsfield Units of the paired (inspiratory/expiratory) chest CT.

The Device outputs DICOM images containing the ventilation output and perfusion output, consisting of a series of image slices generated with the same slice spacing as the expiration CT. In each slice the intensity value for each voxel represents either the value of ventilation or the value for perfusion, respectively, at that spatial location. Additional Information sheet is also generated containing quantitative data, such as lung volume.

5. Indications for Use

CT:VQ software is a non-invasive image post-processing technology, using CT lung images to provide clinical decision support for thoracic disease diagnosis and management in adult patients. It utilizes two non-contrast chest CT studies to quantify and visualize ventilation and perfusion.

Quantification and visualizations are provided as DICOM images. CT:VQ may be used when Radiologists, Pulmonologists, and/or Nuclear Medicine Physicians need a better understanding of a patient's lung function and/or respiratory condition.

6. Substantial Equivalence

Table 1 Summary of subject, primary predicate and secondary predicate device.

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
Device Information			
Name of the Device	CT:VQ	CT Lung Ventilation Analysis Software	CSBP-001A; Body Organ Perfusion System
Abbreviation in this comparison	CT:VQ	CT LVAS, CT:V	CSBP-001A
510(k) number	K251484	K232392	K090504
Manufacturer of the Device	4DMedical Limited	4DMedical Limited	Toshiba America Medical Systems, Inc.
Regulatory Comparison			
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	21 CFR 892.1750
Risk Classification	Class II	Class II	Class II
Primary Product Code	JAK	JAK	JAK
Secondary Product Code	-	-	-
Regulation Name	System, X-Ray, Tomography, Computed	System, X-Ray, Tomography, Computed	System, X-Ray, Tomography, Computed
Users			
Intended User	Radiologists, Pulmonologists, and/or Nuclear Medicine Physicians	Physicians, thoracic radiologists, and pulmonologists.	Physicians
Patient Population	Adult patients	Adult patients	Not specified – Assumed to be at least adult patients
Software Documentation Level	Basic	Basic	Unknown, likely moderate
Principles of Operation / Technical Characteristics	The software input is a non-contrast inspiration/expiration CT, and the output is regional ventilation and regional perfusion measures. These regional measures are derived from the lung tissue displacement, the lung volume change, and the Hounsfield Units of the paired (inspiratory/ expiratory) chest CT.	The software input is a non-contrast inspiration/expiration CT, and the output is regional ventilation measures. These regional measures are derived from the lung tissue displacement and lung volume change between the paired (inspiration/ expiration) chest CTs.	The software input is dynamic CT data acquired after the injection of contrast media and the output is perfusion measures. These measures are calculated by assessing reconstructed data from dynamic (time lapsed collections) CT volume scans.

Table 2 Indication, Intended Use and Device Description Comparison

Characteristic	Subject Device CT:VQ	Primary Predicate Device CT LVAS	Secondary Predicate Device CSBP-001A	Comparison
Indication for Use	CT:VQ software is a non-invasive image post-processing technology, using CT lung images to provide clinical decision support for thoracic disease diagnosis and management in adult patients. It utilizes two non-contrast chest CT studies to quantify and visualize ventilation and perfusion. Quantification and visualizations are provided as DICOM images. CT:VQ may be used when Radiologists, Pulmonologists, and/or Nuclear Medicine Physicians need a better understanding of a patient's lung function and/or respiratory condition.	CT:V software is a non-invasive image processing technology that measures volume changes from paired inspiration-expiration CTs to quantify and visualize regional and global ventilation. These regional measures are derived entirely from the lung tissue displacement and lung volume change between the paired inspiration-expiration chest CTs. CT:V is for use in adult patients. Quantification and visualizations are provided in the form of a report. CT:V may be used when physicians need a better understanding of a patient's lung function and/or respiratory condition	The Body Perfusion System software package is a non-invasive post processing package that has been designed to evaluate perfusion of organs and tumors. The software can calculate blood flow, blood volume and permeability from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media. The software also allows the separate calculation of the arterial and portal venous component of hepatic perfusion. It supports evaluation of regions of interest and the visual inspection of time density curves. When used by a qualified physician a potential application is to differentiate blood flow between normal and diseased tissue. Determination of the change of perfusion parameters during the course of treatment may be helpful in therapy monitoring. It should be used by a trained and qualified physician.	Substantially Equivalent. These devices are all non-invasive software devices that utilize data extracted from x-ray images. The subject device and primary predicate device both possess the functionality to quantify and visualize ventilation measurements of lung tissue. The subject device and the secondary predicate device both possess the functionality to quantify and visualize perfusion measures. The subject device is designed to measure the lungs using a contrast-free CT, while CSBP-001A can evaluate perfusion of any organ but requires the use of a contrast media.
Intended Use	CT:VQ is intended to be used by referral from Radiologists, Pulmonologists, and/or Nuclear Medicine Physicians or equivalent. The CT:VQ software can	The CT:V is intended to be used by referral from thoracic radiologists, pulmonologists or equivalent. The CT LVAS software can be used to provide these physicians with additional	The Body Perfusion System software package is a non-invasive post-processing package that has been designed to evaluate perfusion of organs and tumors. The software can calculate	Substantially Equivalent. There is substantial equivalence in both the User and the patients of these devices. They are

Characteristic	Subject Device CT:VQ	Primary Predicate Device CT LVAS	Secondary Predicate Device CSBP-001A	Comparison
	be used to provide these physicians with additional supporting clinical data regarding pulmonary ventilation and perfusion for use in adult patients.	supporting clinical data regarding pulmonary ventilation for use in adult patients.	blood flow, blood volume and permeability from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media. The software also allows the separate calculation of the arterial and portal venous component of hepatic perfusion. It supports evaluation of regions of interest and the visual inspection of time density curves. When used by a qualified physician a potential application is to differentiate blood flow between normal and diseased tissue. Determination of the change of perfusion parameters during the course of treatment may be helpful in therapy monitoring. It should be used by a trained and qualified physician	intended for use with adult patients; the use with adult patients is assumed for CSBP-001A, as it is not explicitly described in the intended use, but is supported by the data presented in support of K090504. Both Ventilation and Perfusion outputs are intended to be used to support physicians in clinical activities such as monitoring and management of relevant patients conditions.

7. Testing

The CT:VQ software was designed, developed, and tested in accordance with the ISO62304 standard. Known hazards were identified and mitigated in accordance with the ISO14971 standard. Unit level, performance, and integrated system testing were performed. The results of the testing demonstrate that the device is effective and meets the manufacturer's intended performance criteria. Clinical studies were also conducted to demonstrate the safety and efficacy of the device outputs to achieve the intended purpose in the target population in the context of clinical care.

7.1 Verification

4DMedical has conducted performance testing of CT:VQ on a broad combination of synthetically generated phantom images and clinically-acquired datasets. The clinically-acquired data included paired chest CTs acquired on CT scanners across a range of manufacturers and models and at

different institutions, across a diverse range of patients. It also included inspiration and expiration CTs of varying lung volume and image properties. The input CT properties most affecting the quantitative measurements are voxel size and signal-to-noise-ratio (SNR). The verification testing demonstrated that the Device was robust within acceptable performance limits across the entire range of these inputs.

7.2 Clinical Studies

The performance of CT:VQ was assessed across multiple clinical studies, and across the diverse patient population typically referred for nuclear VQ imaging. The studies included patients across the spectrum of lung health and included subjects with pulmonary thromboembolic disease, chronic pulmonary disease (such as Chronic Obstructive Pulmonary Disease and small airways disease), and subjects awaiting pulmonary interventions (such as lung volume reduction therapy). The studies compared the regional ventilation and perfusion measurements output by CT:VQ with gold-standard and best practice measures for respiratory diagnosis. Specifically, the performance of the Device was assessed quantitatively and qualitatively to determine consistency of the Device's outputs with Nuclear Medicine Imaging (Single photon emission computed tomography, SPECT/CT) and pulmonary function tests (Diffusing capacity of the lung for carbon monoxide (DLCO) and FEV1/FVC ratio).

A Reader Performance Study was performed with n=77, while a Standalone Performance Assessment was performed with a subset of 58.

In the **Standalone Performance Assessment**, CT:VQ showed strong regional agreement with SPECT VQ across lobar distributions of ventilation and perfusion. Quantitative perfusion heterogeneity metrics derived from CT:VQ demonstrated stronger associations with gas transfer impairment (DLCO) than those derived from SPECT, suggesting improved physiological sensitivity. Similarly, ventilation heterogeneity metrics from CT:VQ correlated well with FEV1 and FEV1/FVC % predicted, further supporting the clinical relevance of the CT-based outputs.

In the **Reader Performance Study**, clinicians with expertise in thoracic imaging and pulmonary care consistently rated CT:VQ outputs as having *good* to *excellent* agreement with SPECT across all lung regions. Inter-reader variability was not significantly different for CT:VQ than for SPECT, adding to the overall very strong inter-modality agreement. These findings affirm that CT:VQ outputs are interpretable and clinically actionable by intended users.

Case Studies further illustrated key advantages of CT:VQ, including higher spatial resolution and the absence of common SPECT-related artifacts such as esophageal contamination and central airway deposition. In each case, CT:VQ successfully replicated the diagnostic findings of SPECT while offering enhanced image clarity and anatomical fidelity.

The clinical studies conducted for the Device successfully demonstrated the feasibility of generating valid data that is reliable and consistent with Nuclear Medicine Ventilation imaging results. The studies demonstrated strong correlation between CT:VQ and SPECT in the assessment

of regional distribution of ventilation and perfusion and that there was a statistically significant correlation between the CT:VQ and PFT outputs.Based on the clinical performance documented in the clinical studies, CT:VQ was found to have a safety and effectiveness profile that is similar to the primary predicate device. Further, it demonstrated the capability of the Device to provide this information without the use of contrast agents utilized by alternative methods.

8. Consensus Standards

General software verification and validation tests were conducted to confirm the proper function of the device's features. The CT:VQ Analysis Software complies with the following voluntary recognized consensus standards:

- ANSI AAMI ISO14971:2019 Medical Devices – Applications of Risk Management to Medical Devices
- ISO15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ISO14155: 2020 Clinical investigation of medical devices for Human Subjects- Good clinical practices
- ISO20417:2021 Medical devices - Information to be supplied by the manufacturer
- ANSI AAMI IEC62366-1: 2015/Amd 1:2020 Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
- ANSI AAMI IEC62304:2006/Amd 1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- IEC82304-1:2016 Health software - Part 1: General requirements for product safety
- IEEE11073-40101:2020 Health informatics — Device interoperability — Part 40101: Foundational — Cybersecurity — Processes for vulnerability assessment
- IEEE11073-40102:2020 Health informatics — Device interoperability — Part 40102: Foundational — Cybersecurity — Capabilities for mitigation
- FDA Guidance "Content of Premarket Submissions for Device Software Functions" 14June2023
- FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" 26June2025

9. Conclusion as to Substantial Equivalence

The subject device, CT:VQ, has a substantially equivalent intended use, safety, efficacy and similar technological functionalities to the predicate devices CT LVAS and CSBP-001A; Body Organ Perfusion System. Due to the use of publicly available evidence, we cannot claim the technological function of the secondary device is the same as the subject device, however, in principle it is considered SaMD and operates in a manner sufficiently similar to justify its use as a functional predicate.

As described in this document, the differences and similarities drawn between the subject device and the predicate devices did not indicate significant deviation on the intended use, safety or effectiveness between the subject, primary and secondary predicate. 4DMedical has applied QSR 21 CFR Part 820 and ISO13485:2016 quality system requirements with respect to device design and considers the subject device CT:VQ Analysis Software to be as safe, as effective, and its performance to be substantially equivalent to the predicate devices presented.