May 20, 2026

Canon Medical Systems Corporation
% Yoshiaki Cook
Sr. Manager, Regulatory Affairs
Canon Medical Systems, Usa
2441 Michelle Dr.
TUSTIN, CA 92780

Re: K253596
Trade/Device Name: Aquilion ONE (TSX-308A/TSX-306A) V2.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November 17, 2025
Received: November 18, 2025

Dear Yoshiaki Cook:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Radiologic 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)*
K253596

Device Name
Aquilion ONE (TSX-308A/TSX-306A) V2.0

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.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

AiCE 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.

The spectral imaging system utilizes two scan modes: spectral imaging scan and dual energy scan.
The spectral imaging scan allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid kV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies.

The dual energy scan, utilized for brain imaging, allows the system to acquire two CT images of the same anatomical location using distinct tube voltages and/or tube currents during two tube rotations. The X-ray dose will be the sum of the dose of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies.

This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials.

Performance of dual energy scan may be affected by body size and motion artifacts.

When used by a qualified physician, a potential application is to determine the course of treatment.

PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac, abdomen and pelvis and lung applications, in comparison to FBP and hybrid iterative reconstruction.

CLEAR Motion is a Deep Learning Reconstruction (DLR) method designed to reduce motion artifacts. A Deep Convolutional Neural Network (DCNN) is used to estimate the patient's motion. This information is used in the reconstruction process to obtain lung and cardiac images with less motion artifacts.

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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CANON MEDICAL SYSTEMS USA, INC.

Made For life

510(k) SUMMARY

1. SUBMITTER'S NAME:

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2. ESTABLISHMENT REGISTRATION:

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON:

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4. DATE PREPARED:

November 17, 2025

5. TRADE NAME(S):

Aquilion ONE (TSX-308A/TSX-306A) V2.0

6. COMMON NAME:

System, X-ray, Computed Tomography System

7. DEVICE CLASSIFICATION:

Classification Name: Computed Tomography X-ray system
Regulation Number: 21 CFR §892.1750
Regulatory Class: Class II

8. 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
Aquilion ONE (TSX-308A) V1.5	Canon Medical Systems USA	21 CFR §892.1750	Computed Tomography System	JAK	K242403	12/23/2024

11. REASON FOR SUBMISSION:

Modification of a cleared device

12. DEVICE DESCRIPTION:

The Aquilion ONE (TSX-308A/TSX-306A) V2.0 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 (TSX-308A/TSX-306A) 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.

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.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

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The spectral imaging system utilizes two scan modes: spectral imaging scan and dual energy scan. The spectral imaging scan allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid kV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies.

The dual energy scan, utilized for brain imaging, allows the system to acquire two CT images of the same anatomical location using distinct tube voltages and/or tube currents during two tube rotations. The X-ray dose will be the sum of the dose of each tube rotation at its respective tube

voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies.
This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials.
Performance of dual energy scan may be affected by body size and motion artifacts.
When used by a qualified physician, a potential application is to determine the course of treatment.

PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac, abdomen and pelvis and lung applications, in comparison to FBP and hybrid iterative reconstruction.

CLEAR Motion is a Deep Learning Reconstruction (DLR) method designed to reduce motion artifacts. A Deep Convolutional Neural Network (DCNN) is used to estimate the patient's motion. This information is used in the reconstruction process to obtain lung and cardiac images with less motion artifacts.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE (TSX-308A/TSX-306A) V2.0** is substantially equivalent to Aquilion ONE (TSX-308A/3) V1.5, which received premarket clearance under K242403, and is currently marketed by Canon Medical Systems USA.

The subject and predicate devices are the same with the only differences being: Expansion of the use of CLEAR motion to include an option for the Cardiac anatomical region, implementation of the Dual Energy volume scan for the Spectral Imaging System for the acquisition of brain and soft tissue MSK images as a user option, and retraining of the existing PIQE Lung algorithm to improve image quality with particular respect to visualization of cyst walls and vessels.

A comparison of the relevant technological characteristics between the subject and the predicate device is included below.

	Subject Device	**Predicate Device**
Device Name, Model Number	**Aquilion ONE (TSX-308A/TSX-306A) V2.0**	**Aquilion ONE (TSX-308A/TSX-306A) V1.5**
510(k) Number	**This submission**	**K242403**
CLEAR Motion Reconstruction Function	- Lung - Lung Sharp - Body - Body Sharp - Cardiac	- Lung - Lung Sharp - Body - Body Sharp
Spectral Imaging System Scan Regions	- Body - Chest - Extremities - Cardiac - Brain: *Dual Energy volume scan only	- Body - Chest - Extremities - Cardiac

	Subject Device	Predicate Device
Device Name, Model Number	**Aquilion ONE (TSX-308A/TSX-306A) V2.0**	**Aquilion ONE (TSX-308A/TSX-306A) V1.5**
510(k) Number	**This submission**	**K242403**
	- Soft tissue MSK: *Dual Energy volume scan only	
PIQE Algorithm Lung network	PIQE (Precise IQ Engine) * To improve the image quality with particular respect to depiction of cyst walls and vessels, the PIQE Lung network was retrained using additional clinical images. There are no changes in the other reconstruction parameters.	PIQE (Precision IQ Engine)

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, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC81001-5-1, IEC62366-1, NEMA XR-25, NEMA XR-26, 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.

16. TESTING

Risk analysis and verification/validation activities conducted through bench testing demonstrate that the established specifications for the device have been met.

16a. CLEAR Motion for Cardiac

CLEAR Motion is an existing AI-based reconstruction system used for CT scanning with Canon products. Specifically, subject to this submission, Cardiac CLEAR Motion was updated to include the cardiac region, to help reduce motion blur caused by the beating heart.

The cardiac motion correction algorithm was modified to improve image quality in CT scans by compensating for motion in both coronary arteries and other cardiac structures such as ventricles and valves using deep convolutional neural networks (DCNNs) to estimate motion fields from partial image reconstructions. These modifications produce sharper, motion-free cardiac images for improved diagnostic accuracy. Development and training of the algorithm utilized a diverse clinical dataset comprising 114 cardiac CT cases from Aquilion One, Vision, and Genesis systems, covering a wide range of scan parameters, doses, heart rates, and anatomical variations. A total of 3,400 image pairs were used to train the neural network, ensuring robustness across clinically relevant conditions.

Performance Testing - CLEAR Motion IQ Report Phantom Studies

The CLEAR Motion Cardiac algorithm was evaluated using a water phantom to confirm its performance and accuracy. The objective of these evaluations was to verify that the algorithm functions as intended and that the CT number differences between CLEAR Motion and standard reconstructions remain within ±5 Hounsfield Units (HU). One test was conducted using ECG-gated volume scans at 120 kV, 0.5 mm slice thickness, and standard cardiac reconstruction

settings (AIDR3D L3 and AiCE L2). The results showed that CLEAR Motion reconstruction was successfully performed and met the acceptance criteria. The mean CT number differences were −0.09 HU for AIDR3D and −0.08 HU for AiCE, confirming that the algorithm does not introduce significant deviations. Another study was conducted across multiple tube voltage settings (70, 80, 100, 120, and 135 kV). Scans were performed using ECG-gated volume acquisition with consistent parameters (0.5 mm slice thickness, 0.24 sec/rotation, 300 mA). Reconstructions were performed using both AIDR3D Enhanced L2 and AiCE L2 methods. Results showed that CLEAR Motion reconstruction was successfully performed at all kVp settings and met the acceptance criteria. CT number differences between CLEAR Motion and standard images were minimal, ranging from −0.12 to −0.52 HU, confirming the algorithm's consistency and reliability across varying scan conditions. These findings support the safety and effectiveness of CLEAR Motion Cardiac for clinical use.

Performance Testing – CLEAR Motion IQ Report Clinical Image

The CLEAR Motion Cardiac algorithm was evaluated using clinical cardiac CT datasets to confirm its effectiveness in reducing motion artifacts. The objective was to demonstrate that CLEAR Motion improves image quality without introducing significant distortions or loss of anatomical structures. The evaluation involved visual comparisons of images reconstructed using standard methods (AIDR3D, AiCE, and PIQE) and those reconstructed with CLEAR Motion applied. Results showed that CLEAR Motion consistently reduced motion artifacts, particularly around coronary arteries, while maintaining comparable CT number and image noise (standard deviation) trends. Additionally, tests confirmed that image quality remained stable across different display field-of-view (dFOV) settings. These findings support the clinical safety and effectiveness of CLEAR Motion Cardiac for enhancing diagnostic image quality in cardiac CT.

Performance Testing – CLEAR Motion Cardiac Representative Clinical Images Evaluation

Clinical evaluation of CLEAR Motion applied to cardiac and lung CT imaging was conducted by two (2) board-certified radiologists using representative cases from Aquilion ONE systems. Evaluators assessed image quality based on pre-specified criteria including contrast resolution, image noise, spatial detail, and low contrast detectability. A representative sample of eleven (11) total male and female patients, BMI: 25.2-40.2, Age: 31-83, acquired entirely from the U.S make up the representative cases for this study. An AI-based motion correction algorithm, CLEAR Motion, was applied to PIQE reconstructions and compared to standard reconstructions. Across all cases, CLEAR Motion consistently improved spatial detail and reduced motion artifacts, particularly in coronary arteries and lung parenchyma. All image sets were determined to be of diagnostic quality, confirming the safety and effectiveness of CLEAR Motion in enhancing CT image quality.

<u>16b. PIQE Lung Algorithm Retraining</u>

PIQE Lung is an existing AI tool used in Canon products during CT scans of the lungs which helps make images clearer by reducing noise and improving detail.

Subject this submission, the PIQE Lung network was retrained using additional clinical images, for the purpose of improving the depiction of cyst walls and vessels. There are no changes in the other reconstruction parameters. This was achieved by modifying the algorithm by integration of a deep convolutional neural network (DCNN) to improve image resolution and reduce noise in lung CT scans for enhanced diagnostic image quality, particularly in low-dose scans, by better distinguishing true anatomical signals from noise. The algorithm was trained using high-resolution CT images (AiCE from Aquilion Precision) as targets and simulated lower-resolution,

noisy images as inputs. The clinical dataset used during development included nine ultra-high-resolution lung cases and one high-resolution case from Aquilion Insight, covering a range of dose levels and anatomical variations. A set of ten (10) total male and female patients, BMI: 22.1-42.0, Age: 32-67, acquired entirely from the U.S. was used as the representative set for this study.

Training data were reconstructed using an approach which enabled the algorithm to learn both noise reduction and resolution enhancement across clinically relevant conditions.

Performance Testing – PIQE Lung IQ Report – Phantom Study

The PIQE Lung algorithm was evaluated using phantom studies to confirm its performance and image quality improvements. The objective was to verify that PIQE Lung reconstruction reduces image noise and maintains structural integrity compared to standard AIDR3D Lung reconstruction. Tests were conducted using a water phantom and CATPHAN models (CTP404, CTP515, CTP528) across a range of dose levels (15–250 mAs). The evaluation confirmed that PIQE Lung reconstructions showed improved image noise (lower standard deviation) and no significant artifacts or structural distortions. CT number differences between PIQE and standard reconstructions remained within acceptable limits. These results demonstrate that PIQE Lung functions as intended and supports safe and effective use in clinical imaging.

Performance Testing – PIQE Lung IQ Report – Clinical Imaging

The PIQE Lung algorithm was evaluated using clinical CT data to confirm its effectiveness in improving image quality. The objective was to compare PIQE Lung reconstructions to standard AIDR3D Lung images and assess improvements in image noise and spatial resolution. Evaluations were performed visually and by measuring image standard deviation (SD) in uniform regions. The study confirmed that PIQE Lung reconstructions showed reduced image noise and enhanced spatial detail without introducing significant artifacts or structural distortions. Additionally, performance remained consistent across different display field-of-view (dFOV) settings. These results support the safety and effectiveness of PIQE Lung for clinical use in lung imaging.

Performance Testing- PIQE Lung Representative Clinical Images Evaluation

Clinical evaluation of PIQE with V2.0 software was conducted by two (2) board-certified radiologists using representative lung CT cases. A set of ten (10) total male and female patients, BMI: 22.1-42.0, Age: 32-67, acquired entirely from the U.S. was used as the representative set for this study. Evaluators assessed image quality based on pre-specified criteria including contrast resolution, image noise, spatial detail, and low contrast detectability. Each case was reviewed using both PIQE previously cleared under K242403 and PIQE with V2.0 software reconstructions. All image sets were determined to be of diagnostic quality, with PIQE with V2.0 software consistently showing improved spatial detail and reduced image noise. The evaluation used a standardized scoring scale (1–5), and all cases received average scores of 4 or higher, indicating good to excellent diagnostic image quality. The AI-based PIQE algorithm demonstrated enhanced visualization of lung structures, including cysts, nodules, and ground-glass opacities, supporting its safety and effectiveness for clinical use.

16c. Dual Energy Volume Scans for Brain and Soft Tissue MSK for the Spectral Imaging System

In this submission, available scan regions are expanded to include the brain and soft tissue MSK regions. Only Dual Energy (DE) volume scans are available for these added regions, at present.

Performance Testing – Dual Energy Volume Scans Image Quality (IQ) Metric Evaluation
The iodine quantification capability of the spectral imaging feature was evaluated using the Aquilion ONE systems with V2.0 SP0000 software. The objective was to confirm that iodine concentration measurements in iodine map images show a linear correlation with known iodine concentrations. The results of this testing confirm the accuracy and reliability of iodine quantification in spectral imaging, supporting its safe and effective use in clinical applications.

Performance Testing - Dual Energy Volume Scans Representative Clinical Images Evaluation
Clinical evaluation of dual energy CT imaging was conducted by a board-certified radiologist using representative brain and musculoskeletal (MSK) cases from Aquilion ONE V2.0 subject device. It was confirmed that the reconstructed images using the subject device were of diagnostic quality.

All prespecified acceptance criteria for performance were passed, demonstrating the substantial equivalence by the improved features relative to the existing features upon which they were predicated.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, is included in this submission. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation, per the FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", issued on June 27, 2025, was included in this submission.

17. CONCLUSION

The **Aquilion ONE (TSX-308A/TSX-306A) V2.0** 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 as safe and effective for its intended use.