



September 12, 2024

Canon Medical Systems Corporation
% Yoshiaki Cook
Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Dr
Tustin, California 92780

Re: K241582

Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: August 12, 2024
Received: August 13, 2024

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 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.

Assistant Director

Mammography and Ultrasound Team

DHT8C: Division of Radiological

Imaging and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K241582

Device Name

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0

Indications for Use (Describe)

The Diagnostic Ultrasound System Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700 are indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs (thyroid, breast and testicle), trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial), laparoscopic and Thoracic/Pleural. This system provides high-quality ultrasound images in the following modes B mode, M mode, Continuous Wave, Color Doppler, Pulsed Wave Doppler, Power Doppler and Combination Doppler, as well as Speckle-tracking, Tissue Harmonic Imaging, Combined Modes, Shear wave, Elastography, and Acoustic attenuation mapping. This system is suitable for use in hospital and clinical settings by physicians or legally qualified persons who have received the appropriate training.

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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K241582**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

May 31, 2024

5. DEVICE NAME/TRADE NAME

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0

6. COMMON NAME

System, Diagnostic Ultrasound

7. DEVICE CLASSIFICATION

Class II
Ultrasonic Pulsed Doppler Imaging System – Product Code: IYN [per 21 CFR 892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: IYO [per 21 CFR 892.1560]
Diagnostic Ultrasonic Transducer – Product Code: ITX [per 21 CFR 892.1570]
Medical Image Management and Processing System – Product Code: QIH [per 21 CFR 892.2050]

8. PREDICATE DEVICE

Product	Marketed by	510(k) Number	Clearance Date
Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0	Canon Medical Systems USA, Inc.	K223017	March 31, 2023

9. REASON FOR SUBMISSION

Modification of a cleared device.

10. DEVICE DESCRIPTION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700, V7.0 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex, and sector array with frequency ranges between approximately 2MHz to 33MHz.

11. INDICATIONS FOR USE

The Diagnostic Ultrasound System Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700 are indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs (thyroid, breast and testicle), trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial), laparoscopic and Thoracic/Pleural. This system provides high-quality ultrasound images in the following modes: B mode, M mode, Continuous Wave, Color Doppler, Pulsed Wave Doppler, Power Doppler and Combination Doppler, as well as Speckle-tracking, Tissue Harmonic Imaging, Combined Modes, Shear wave, Elastography, and Acoustic attenuation mapping. This system is suitable for use in hospital and clinical settings by physicians or legally qualified persons who have received the appropriate training.

12. SUBSTANTIAL EQUIVALENCE

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V7.0 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V7.0 (K223017). The subject devices employ the same fundamental scientific technology as the predicate devices and function in a manner similar to and are intended for the same use as the predicate devices. The subject devices include improvements to existing features and functionality. This submission includes details which demonstrate the substantial equivalence of the improved features, to those currently cleared with the predicate device.

- The subject Aplio i900/i800/i700, V7.0 and predicate Aplio i900/i800/i700, V7.0 have the same clinical intended use and use the same imaging modes
- The transducers supported by the subject and predicate Aplio i900/i800/i700 systems are identical
- The software features supported in the subject Aplio i900/i800/i700, V7.0 and predicate Aplio i900/i800/i700, V7.0 are identical except for the following improvements to features or functionality available with predicate Aplio i900/i800/i700, V7.0

- Auto Plane Detection, which introduces a deep learning method to the existing 2D Wall Motion Tracking (WMT) feature for the automatic selection of appropriate candidate cardiac views (A4C/A2C/A3C/SAX)
- Quick Strain, which operates in conjunction with Auto Plane Detection to enable 2D WMT LV to be launched simultaneously for A4C, A3C, and A2C cardiac views
- Auto LVOT, an improvement to existing non-AI Doppler trace measurement methods, by introducing a deep learning method to trace LVOT Doppler waveforms
- Auto AoV, an improvement to existing non-AI Doppler trace measurement methods, by introducing a deep learning method to trace AV Doppler waveforms
- 2D WMT RV, which enables the expansion of existing Wall Motion Tracking functionality for the right ventricle
- 2D WMT RA, which enables the expansion of existing Wall Motion Tracking functionality for the right atrium

14. SAFETY

The subject devices are designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. These devices are in conformance with the applicable parts of the ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012(Cons. Text) [Incl. AMD2:2021], IEC 60601-1-2 (2020), IEC 60601-2-37 (2015), IEC 62304 (2015), IEC 62359 (2017) and ISO 10993-1 (2018) standards.

15. TESTING

Risk Analysis and verification and validation activities demonstrate that the established specifications for these devices have been met. Additional performance testing included in the submission was conducted in order to demonstrate that the requirements for the improved features were met. The results of all these studies demonstrate that the improved features meet established specifications and perform as intended and in accordance with labeling.

FDA guidance document “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”, issued February 21, 2023, was referenced for this submission, and software documentation appropriate for the Basic Documentation Level, per the FDA guidance document, “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023, was included in this submission.

Additionally, cybersecurity documentation, per the FDA guidance document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”, issued on September 27, 2023, was included in this submission.

Testing of this device was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and UL systems.

Validation of improved AI/ML based features:

The data used for the performance testing of these improved features was entirely independent and sequestered from the data used for training and was acquired from U.S. clinical patients with the predicate device, identical to the subject device in terms of data acquisition functionality. To validate the performance of these features, predefined inclusion criteria were established to obtain data sets that were representative of the U.S. intended use population with respect to demographic characteristics, including representative BMI and disease severity ranges. A sufficient sampling of important subgroups to support generalizability was present in the test data

set used for each feature. Ground Truth was established by three clinical sonographers with qualifications and clinical experience representative of intended users of these features in the U.S., using existing, 510(k) cleared predicate functionality to establish a baseline against which the performance of the improved AI/ML based features were evaluated. All predefined acceptance criteria for performance were passed, demonstrating the substantial equivalence by the improved features relative to the existing features upon which they were predicated, while simultaneously enabling workflow improvements. Age, gender, BMI and disease severity were evaluated as potential confounders and/or effect modifiers on the performance of these features. An analysis of these subgroups demonstrated that none of the subgroups presented as confounders or effect modifiers on the performance of the improved features, supporting the generalizability of the features to the U.S. intended use population.

Auto Plane Detection:

Auto Plane Detection was evaluated to demonstrate that the results of its selection of candidate cardiac chamber views are substantially equivalent to cardiac chamber views selected by three clinical sonographers with qualifications and expertise representative of U.S. intended users. The acceptance criteria established for this evaluation required that the views automatically selected by this feature, compared to those manually selected by the sonographers demonstrated more than 90% agreement for each of the four evaluated chamber views (A4C/A3C/A2C/SAX). Auto Plane Detection achieved these criteria for each of the four views, with an average pass rate of 97% across these four views. A subgroup analysis by binary logistics regression demonstrated that none of the evaluated variables imparted a significant effect on the performance of Auto Plane Detection. These results demonstrate that this feature can detect the A4C, A3C, A2C and SAX with a more than 90% success rate and that the subgroups represented in the test data set do not present as confounders and/or effect modifiers on the performance of the feature.

Validation data details:

Demographic distribution	This study included representative images from 50 patients selected from among previously acquired data • Gender: roughly equivalent number of males and females • Age: Ranging from 20-98 years old • Ethnicity (Country): USA • BMI: ranging from 16.4-71.6 kg/m², equally distributed across underweight or healthy, overweight, and obese categories • Disease severity: normal, mildly abnormal, moderately abnormal, and severely abnormal categories of left ventricle ejection fraction equivalently represented
Data collection	Images from 239 demographically diverse patients acquired over a two-month period at a U.S. clinical site.
Truthing Method	A licensed sonographer selected representative images for each of the four evaluated chamber views (A4C/A3C/A2C/SAX)

	and two different licensed sonographers independently identified the cardiac view for all selected images, with any discrepancies resolved by consensus among the three.
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Quick Strain:

Quick Strain was evaluated to demonstrate time savings compared to the existing workflow (conventional Wall Motion Tracking for A4C, A2C, and A3C views), while maintaining equivalent wall motion tracking results for the outputs of EDV, ESV, EF and GLS. This study evaluated operation time by 2-way ANOVA analysis, inter-operator variability by Inter Correlation Coefficient (ICC), and analyzed EDV, ESV, EF and GLS results by the Normalized Root Mean Square (NRMSE) between the conventional workflow and subject function. The acceptance criteria established for these evaluated parameters were a reduced operation time by Quick Strain with a significance level of 5%, all ICC(2,1) values by Quick Strain greater than 0.75, and calculated NRMSE for EDV, ESV, EF and GLS by three clinical sonographers of less than 10%. All prespecified performance criteria were passed by Quick Strain which achieved an average 68% reduction in operation time, demonstrated minimal inter-operator variability by adoption of two-way random effects, absolute agreement, single rater/measurement for ICC, and calculated NRMSE results for EDV, ESV, EF and GLS within 10% of the results using existing workflow. A subgroup analysis performed by multiple linear regression demonstrated that none of the evaluated variables impart a significant effect on the performance of Quick Strain. From these results, it was demonstrated that Quick Strain can shorten exam time while producing substantially equivalent results as predicate functionality and that the subgroups represented in the test data set do not present as confounders and/or effect modifiers on the performance of Quick Strain.

Validation data details:

Demographic distribution	This study included images from 50 patients selected from among previously acquired data • Gender: roughly equivalent number of males and females • Age: Ranging from 20-98 years old • Ethnicity (Country): USA • BMI: ranging from 16.4-71.6 kg/m², equally distributed across underweight or healthy, overweight, and obese categories • Disease severity: normal, mildly abnormal, moderately abnormal, and severely abnormal categories of left ventricle ejection fraction equivalently represented
Data collection	Images from 239 demographically diverse patients acquired over a two-month period at a U.S. clinical site.
Truthing Method	Ground truth was established by the median of manual measurement results taken by three licensed sonographers using the

	predicate method (the existing 2D WMT LV feature, without the Quick Strain improvement)
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Auto LVOT:

Auto LVOT was evaluated to demonstrate a time savings by enabling a deep learning method to detect left ventricular outflow tract (LVOT) Doppler waveforms, while producing equivalent trace measurement results as the existing workflow, which requires manual tracing of the LVOT Doppler waveform. This study evaluated operation time by 2-way ANOVA analysis, inter-operator variability by Inter Correlation Coefficient (ICC), and analyzed results by the Normalized Root Mean Square (NRMSE) between the conventional workflow and subject function. The acceptance criteria established for these evaluated parameters were a reduced operation time by Auto LVOT with a significance level of 5%, all ICC(2,1) values by Auto LVOT greater than 0.75, and calculated NRMSE results by three clinical sonographers of less than 10%. In passing all prespecified performance criteria, Auto LVOT demonstrated an average 78% reduction in operation time (3 consecutive heart cycles), minimal inter-operator variability by two-way random effects, absolute agreement, single rater/measurement for ICC, and calculated NRMSE results by each of the three sonographers within 10% of the results using existing workflow. A subgroup analysis by multiple linear regression demonstrated that none of the evaluated variables impart a significant effect on the performance of Auto LVOT. From these results, it was demonstrated that Auto LVOT can shorten exam time while producing substantially equivalent results as predicate functionality and that the subgroups represented in the test data set do not present as confounders and/or effect modifiers on the performance of Auto LVOT.

Validation data details:

Demographic distribution	This study included representative images from 45 patients selected from among previously acquired data • Gender: roughly equivalent number of known males and females* • Age: Ranging from 36-89 years old* • Ethnicity (Country): USA • BMI: ranging from 18.8-71.6 kg/m², equally distributed across underweight or healthy, overweight, and obese categories • Disease severity: normal, low severity, and high severity categories of LVOT velocity time integral range equivalently represented
Data collection	Images from 239 demographically diverse patients acquired over a two-month period at a U.S. clinical site.
Truthing Method	Ground truth was established by the median of manual LVOT measurement results taken by three licensed sonographers

* Due to data anonymization practices during acquisition, the age and gender of 20 patients was unavailable.

Auto AoV:

Auto AoV was evaluated to demonstrate a time savings by enabling a deep learning method to detect aortic valve (AV) Doppler waveforms, while producing equivalent trace measurement results as the existing workflow, which requires manual tracing of the AV Doppler waveform. This study evaluated operation time by 2-way ANOVA analysis, inter-operator variability by Inter Correlation Coefficient (ICC), and analyzed results by the Normalized Root Mean Square (NRMSE) between the conventional workflow and subject function. The acceptance criteria established for these evaluated parameters were a reduced operation time by Auto AoV with a significance level of 5%, all ICC(2,1) values by Auto AoV greater than 0.75, and calculated Doppler trace measurement results by three clinical sonographers of less than 10%. All prespecified performance criteria were passed with demonstration by Auto AoV of an average 71% reduction in operation time (3 consecutive heart cycles), minimal inter-operator variability by two-way random effects, absolute agreement, single rater/measurement for ICC, and calculated NRMSE results by each of the three sonographers within 10% of the results using existing workflow. A subgroup analysis by multiple linear regression model demonstrated that none of the evaluated variables impart a significant effect on the performance of Auto AoV. From these results, it was demonstrated that Auto AoV can shorten exam time while producing substantially equivalent results as predicate functionality and that the subgroups represented in the test data set do not present as confounders and/or effect modifiers on the performance of Auto AoV.

Validation data details:

Demographic distribution	This study included representative images from 45 patients selected from among previously acquired data • Gender: roughly equivalent number of known males and females* • Age: Ranging from 36-89 years old* • Ethnicity (Country): USA • BMI: ranging from 18.8-71.6 kg/m², equally distributed across underweight or healthy, overweight, and obese categories • Disease severity: normal, low severity, and high severity categories of AV velocity time integral range equivalently represented
Data collection	Images from 239 demographically diverse patients acquired over a two-month period at a U.S. clinical site.
Truthing Method	Ground truth was established by the median of manual AV measurement results taken by three licensed sonographers

* Due to data anonymization practices during acquisition, the age and gender of 21 patients was unavailable.

16. CONCLUSION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V7.0 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V7.0, K223017. The subject devices function in a manner similar to and are intended for the same use as the predicate devices, as described in labeling. The evidence provided in this submission demonstrate that Aplio i900/i800/i700, Diagnostic Ultrasound System, V7.0 are safe and effective for their intended use and perform with substantial equivalence to the predicate devices.