



October 31, 2025

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

Re: K252074

Trade/Device Name: Aplio i900, Aplio i800 and Aplio i700 Software V9.0 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic Pulsed Doppler Imaging System

Regulatory Class: Class II

Product Code: IYN, IYO, ITX, QIH

Dated: October 3, 2025

Received: October 3, 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 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)

K252074

Device Name

Aplio i900, Aplio i800 and Aplio i700 Software V9.0 Diagnostic Ultrasound System

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 appropriately trained healthcare professionals.

In addition to the aforementioned indications for use, when EUS transducer GF-UCT180 and BF-UC190F are connected, Aplio i800 Model TUS-AI800/E3 provides image information for diagnosis of the upper gastrointestinal tract and surrounding organs, airways, tracheobronchial tree and esophagus.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K252074**510(k) SUMMARY****1. SUBMITTER'S NAME**

Junichiro Araoka
Sr. Manager, Quality Assurance Dept.
Quality, Safety and Regulation Center
Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-ken, Japan 324-8550

2. ESTABLISHMENT REGISTRATION

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON

Yoshiaki Cook
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, CA 92780
ycook@us.medical.canon
+1 (657) 270-5595

4. DATE PREPARED

July 01, 2025

5. DEVICE NAME/TRADE NAME

Aplio i900, Aplio i800 and Aplio i700 Software V9.0 Diagnostic Ultrasound System

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 V8.5	Canon Medical Systems USA, Inc.	K242808	May 13, 2025

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, V9.0 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 appropriately trained healthcare professionals.

In addition to the aforementioned indications for use, when EUS transducer GF-UCT180 and BF-UC190F are connected, Aplio i800 Model TUS-AI800/E3 provides image information for diagnosis of the upper gastrointestinal tract and surrounding organs, airways, tracheobronchial tree and esophagus.

12. SUBSTANTIAL EQUIVALENCE

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V9.0 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V8.5 (K242808). 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 new features, as well as improvements to existing functionality. These differences between the subject devices and cleared predicate devices do not raise any new questions about the safety and effectiveness of the subject devices. This submission includes details which demonstrate the substantial equivalence of the improved features, to those currently cleared with the predicate device.

- The subject devices have the same clinical intended use and use the same imaging modes as the predicate devices

- The transducers supported by the subject and predicate devices are identical
- The software features and functionality supported in the subject and predicate devices are identical except for the following
 - 3rd Harmonic Imaging (3-HI), a new deep learning (DL) enabled filtering process for images of the abdominal region, which enables higher spatial resolution, contrast resolution, and reduced artifacts
 - SMI Angio Mode, an improvement to the SMI functionality available with the predicate device, which emphasizes separation of adjacent blood flows
 - Precision+ Fine Processing Mode, an improvement to existing Precision+ functionality, to enable improved depiction of borders
 - Auto Tune, and improvement to existing Shear wave elasticity(SWE) and Shear wave dispersion(SWD) functionality, which introduces a pre-scan which optimizes scan conditions in advance of the main scan for more accurate SWE results
 - The operating system incorporated in the subject devices will be changed to Windows 11 LTSC due to the forthcoming termination of support of the Windows 10 LTSC incorporated in the predicate devices

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 new and improved features and functionality were met. The results of all these studies demonstrate that the subject devices 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 June 27, 2025, 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 Ultrasound systems.

Validation of improvements to existing features

SMI Angio Mode

SMI Angio Mode is introduced as an improvement to the existing SMI feature, to emphasize the separation of adjacent blood flows. This improved functionality was tested using phantom data

and clinical images acquired from three volunteers. All prespecified performance criteria were achieved, confirming that the improved SMI Angio Mode performs as intended and emphasizes the separation of adjacent blood flow compared with the predicate function.

Auto Tune

Auto Tune is introduced as an improvement to the existing Shear wave elasticity (SWE) and Shear wave dispersion (SWD) features, to enable a pre-scan which optimizes scan conditions in advance of the subsequent SWE or SWD main scan to achieve more accurate SWE results. This study utilized phantom data as well as images of the thyroid and liver acquired from three volunteers. All prespecified performance criteria were achieved, confirming that Auto Tune performs as intended.

Precision+ Fine Processing Mode

Precision+ Fine Processing Mode is an improvement in the functionality of the existing Precision+ feature, to improve the depiction of borders in an image. This test compared clinical images acquired using a standard preset, to which both the Precision+ Fine Processing Mode and predicate functionality, Precision+ were applied. The images were acquired from anatomy representative of the intended use of Precision+ Fine Processing Mode and in all cases, improved visibility of tissue structure was demonstrated when using Precision+ Fine Processing Mode, confirming it achieves its purpose as an improvement of the existing Precision+ feature.

Validation of new DL based feature, 3rd Harmonic Imaging (3-HI)

This clinical evaluation was conducted in order to demonstrate improvement relative to predicate functionality (conventional 2nd harmonic imaging), with respect to spatial resolution, contrast resolution, and artifact suppression. The evaluation was conducted using abdominal images acquired from 30 patients from a U.S. clinical site. The validation data set was entirely independent of the data set used to train the algorithm during its development. The algorithm was locked upon completion of development, prior to implementation into the 3-HI feature and no post-market, continuous learning capability is deployed on the subject device. Inclusion criteria specified adult patients clinically scheduled for abdominal or pelvic imaging, or patients with a prior diagnosis of focal pathologies of the abdomen or pelvis. Images of representative organs and anatomical structures and representative focal pathologies were included in the study to simulate expected clinical variation encountered by this feature during clinical use. Patients were selected to ensure diverse demographic characteristics representative of the intended U.S. patient population, including a wide range of body mass indices. Three (3) U.S. board certified radiologists participated in a blinded observer study, in which images with 3-HI were compared to images without 3-HI (predicate functionality) using a 5-point ordinal scale. The median score was compared with the middle score of 3. A statistical analysis of the results demonstrated that scores for 3-HI were higher than the middle score of 3 with respect to spatial resolution, contrast resolution, and artifact suppression.

A sub-group analysis was conducted in order to demonstrate the generalizability of the evaluated performance for the intended U.S. patient population, confirming improvement of 3-HI compared with predicate functionality.

Validation details:

Demographic distribution	<p>This study included representative images from 30 patients selected from among previously acquired data</p> <ul style="list-style-type: none"> • Gender: roughly equivalent number of males and females • Age: Ranging from 23-89 years old • Ethnicity (Country): USA • BMI: ranging from 18.5-36.3 kg/m², equally distributed across underweight or healthy, overweight, and obese categories • Images were collected of various representative abdominal organs and anatomical structures, as well as various representative focal pathologies
Data collection	Minimum 294 images from demographically diverse patients acquired at a U.S. clinical site
Evaluation Method	Three (3) board certified U.S. radiologists participate in a blind scoring and visibility evaluation in accordance with Canon’s study design

This clinical evaluation was supplemented by phantom studies which examined the lateral and axial resolution, slice resolution, contrast-to-noise ratio (CNR), reverberation artifact suppression and frequency spectra aspects of image quality. Five abdominal phantoms with various physical properties including targets at depths ranging from 3cm to 11.5cm, various target sizes from pin targets to 10mm targets and targets with high and low contrast were used for the evaluation of lateral and axial resolution, slice resolution and CNR improvements by 3-HI. In passing all prespecified performance criteria, these phantom studies demonstrated the capability of 3-HI to visualize abdominal images better than conventional 2nd harmonic imaging with respect to lateral and axial resolution, slice resolution, CNR, reverberation artifact suppression and frequency spectra aspects of image quality, as well as support the overall finding of improved performance by 3-HI compared to predicate for its intended use.

16. CONCLUSION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V9.0 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V8.5, K242808. 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, V9.0 are safe and effective for their intended use and perform with substantial equivalence to the predicate devices.