January 20, 2026

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

Re: K253597
Trade/Device Name: Aplio beyond and Aplio me Software V2.0 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
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 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,

MARJAN NABILI -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253597

Device Name
Aplio beyond and Aplio me Software V2.0 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Diagnostic Ultrasound System Aplio beyond Model CUS-ABE00, Aplio me Model CUS-AME00 are indicated for the visualization of structures, and dynamic processes within 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.

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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K253597

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. DEVICE NAME/TRADE NAME

Aplio beyond and Aplio me Software V2.0 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]

8. PREDICATE DEVICE

Product	Marketed by	510(k) Number	Clearance Date
Aplio i700 Diagnostic Ultrasound System, Software V8.5 (Primary predicate)	Canon Medical Systems USA, Inc.	K242808	May 13, 2025
Xario200G, Diagnostic Ultrasound System, Software Version 1.1 (Reference device)	Canon Medical Systems USA, Inc.	K182596	November 02, 2018
Aplio flex, Diagnostic Ultrasound System, Software Version 2.0 (Reference device)	Canon Medical Systems USA, Inc.	K232988	November 21, 2023
Aplio a550, Diagnostic Ultrasound System, Software Version 6.5 (Reference device)	Canon Medical Systems USA, Inc.	K212960	March 22, 2022
Aplio i700 Software V9.0 Diagnostic Ultrasound System (Reference device)	Canon Medical Systems USA, Inc.	K252074	October 31, 2025

9. REASON FOR SUBMISSION

New device.

10. DEVICE DESCRIPTION

The Aplio beyond, Model CUS-ABE00 and Aplio me, Model CUS-AME00, V2.0 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 20MHz.

11. INDICATIONS FOR USE

The Diagnostic Ultrasound System Aplio beyond Model CUS-ABE00, Aplio me Model CUS-AME00 are indicated for the visualization of structures, and dynamic processes within 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.

12. SUBSTANTIAL EQUIVALENCE

The Aplio beyond, Model CUS-ABE00 and Aplio me, Model CUS-AME00, V2.0 are substantially equivalent to the Aplio i700 Diagnostic Ultrasound System, Software V8.5 (K242808). The subject devices employ the same fundamental scientific technology as the predicate device and function in a manner similar to, and are intended for the same use as the predicate device. Differences between the subject devices and cleared predicate device do not raise any new questions about the safety and effectiveness of the subject devices. This submission includes evidence to demonstrate the substantial equivalence of the subject devices to the predicate device.

It is noted that the software architecture of the predicate device was migrated, largely unchanged, into the new Aplio beyond and Aplio me, V2.0 devices. Evidence provided in this submission demonstrated the substantial equivalence between the subject and predicate devices, such that any differences were shown to not impart any effect on the previously demonstrated performance of the software features and functionality cleared in the software architecture migrated from the predicate device and confirmed that the software performs as intended when implemented in the subject devices.

- The subject devices have the same clinical intended use and use the same imaging modes as the predicate device, and share the same fundamental technological characteristics differing only by the following:
    - Scanning method: 2D array transducers are not supported by the subject devices; the scanning methods are otherwise identical to those of the predicate device
    - Transmission control: The subject devices, like reference devices Xario200G and Aplio a550, transmit bipolar pulse trains, whereas the predicate device transmits linear pulse trains
    - Transmission/Reception Circuitry: The subject devices, like reference devices Xario200G and Aplio a550, simultaneously receive up to 128 channel signals, while the predicate device simultaneously receives up to 256 channel signals
    - Image processing: The subject devices utilize the same image processing as reference device Aplio a550, apart from one transducer supported by Aplio beyond, for which the image processing of the predicate device is utilized
    - Color Doppler Image Processing: Aplio beyond, like the predicate device, supports Doppler Luminance mode, whereas the Aplio me does not
    - Reference signals: Aplio beyond, like the predicate device, supports ECG, PCG, Pulse and Respiration reference signals, whereas the Aplio me supports ECG
    - Input/Output: The subject devices, unlike the predicate device, do not support DVI video output
- The physical and hardware characteristics of the subject and predicate devices are largely shared, except:
    - A built-in cover for printer or video recorder components and a transducer adaptor, to accommodate the connection of two transducers available with the predicate device, are new hardware features of the subject devices
    - System dimensions: Aspects of system design such as height, depth and width differ from the predicate device to accommodate factors such as customer needs

    - Observation monitor: The Aplio beyond and the predicate device share a standard monitor size (23 in width), only available as an option for the Aplio me, which has a slightly smaller standard monitor size (21.5 in width)
    - Support by the predicate device of a 2nd console and camera functionality, not available with the subject devices
- The transducers newly developed for use with the subject devices employ the same fundamental scientific technology, and are substantially equivalent to those existing with the predicate device, while the remaining transducers supported by the subject devices have been previously cleared with either the predicate or reference devices
- The software features and functionality supported in the subject and predicate devices are largely identical, except for the following:
    - Precision+ Fine Processing, a modification to the Precision feature available with the predicate device, intended to improve image border depiction, implemented in Aplio beyond, but not the predicate device. Precision+ Fine Processing was previously cleared with reference device, Aplio i700 (K252074)
    - Application Measurement: Breast Scan Guide, available with the predicate device, is implemented in Aplio beyond, but not Aplio me
    - Strain ratio measurement: the subject devices, unlike the predicate device, do not support this functionality
    - Shear wave Elastography: The Quad View capability for this feature, available with the predicate device, is supported by Aplio beyond but not Aplio me
    - Software features available with the predicate device which utilize sensor functionality, such as Fusion, Smart Body Mark, Smart Navigation and Breast Package are supported by Aplio beyond but not Aplio me

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 transducers and improved software functionality were met. In addition to software V&V conducted at the subject software version, additional bench testing confirmed that there are no device dependencies which affect the performance of the software cleared with the predicate devices when migrated into the subject devices and therefore, that the previously demonstrated performance of the software is maintained as implemented into the subject devices. 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.

16. CONCLUSION

The Aplio beyond, Model CUS-ABE00 and Aplio me, Model CUS-AME00, V2.0 are substantially equivalent to the Aplio 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 device, as described in labeling. The evidence provided in this submission demonstrates that Aplio beyond and Aplio me, V2.0 are safe and effective for their intended use and perform with substantial equivalence to the predicate device.