May 13, 2025

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

Re: K242808
Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V8.5
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 11, 2025
Received: April 14, 2025

Dear Cook Yoshiaki:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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

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.

Submission Number *(if known)*

K242808

Device Name

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V8.5

Indications for Use *(Describe)*

The Diagnostic Ultrasound System Aplio i900 Model TUS-AI900,Aplio i800 Model TUS-AI800, 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.

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.

510(k) SUMMARY K242808

1. SUBMITTER'S NAME

Fumiaki Teshima
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
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

September 17, 2024

5. DEVICE NAME/TRADE NAME

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V8.5

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 i900/i800/i700 Diagnostic Ultrasound System, Software V8.1 (Primary predicate)	Canon Medical Systems USA, Inc.	K233195	01/24/2024
OLYMPUS EVIS EUS Ultrasound Bronchofibervideoscope BF-UC190F (Reference device)	Olympus Medical Systems Corporation	K183525	09/06/2019

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, V8.5 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.

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, V8.5 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V8.1 (K233195). 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 transducers and improvements to existing software functionality. These differences between the subject devices and the cleared predicated devices do not raise any new questions about the safety and effectiveness of the subject devices.

This submission provides evidence to demonstrate the substantial equivalence of the subject devices and the predicate devices.

- 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 apart from the following, introduced in this submission
    - EUS probe model BF-UC190F, manufactured by Olympus Medical Systems Corporation, available with Aplio i800 Model TUS-AI800/E3
    - Laparoscopic and abdominal probe model PET-835LA, manufactured by Canon Medical Systems Corporation, available with the Aplio i900/i800/i700
    - Transesophageal cardiac probe model PEI-514VX, manufactured by Canon Medical Systems Corporation, available with Aplio i900/i800/i700
    - The indicated uses available with the subject devices are pre-existing with the predicate devices, except for the added imaging of airways, tracheobronchial tree and esophagus, enabled for Aplio i800 Model TUS-AI800/E3 by BF-UC190F
- The software features and functionality supported in the subject and predicate devices are identical except for the following improvements to software functionality available with the predicate devices
    - Several workflow improvements for Cardiac 4D imaging
    - A workflow improvement and an increase in the data storage capacity for Stress Echo functionality
    - Several workflow and image quality improvements including:
        - Migrated support of existing 3D Differential THI functionality for PVT-681MVL
        - 4D MPR mapping image quality improvements, as well as the migration of existing 4D MPR capabilities to additional imaging modes utilized in OB/GYN exams
        - Migration of existing Doppler Luminance display for 3D color data on MPR
        - Workflow and display improvements for the existing Auto Volume Measurement feature
    - Workflow and image quality improvements for Breast exams, including
        - BI-RADS workflow improvements
        - New frequency settings for breast exams
    - Workflow and display enhancements for existing Shear Wave and Attenuation Imaging features
    - DICOM improvement
        - Support of one of “RTSTRUCT” formats output by Siemens workstation.

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. 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 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.

16. CONCLUSION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V8.5 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V8.1, K233195. 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 the Aplio i900/i800/i700, Diagnostic Ultrasound System, V8.5 are safe and effective for their intended use and perform with substantial equivalence to the predicate devices.