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

January 24, 2024

Re: K233195
Trade/Device Name: Aplio i900, Aplio i800 and Aplio i700 Software V8.1 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: December 28, 2023
Received: December 28, 2023

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.

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
Assistant Director
Mammography and Ultrasound Team
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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)*
K233195

Device Name
Aplio i900, Aplio i800 and Aplio i700 Software V8.1 Diagnostic Ultrasound System

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 is connected, Aplio i800 Model TUS-AI800 /E3 provides image information for diagnosis of the upper gastrointestinal tract and surrounding organs.

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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510(k) SUMMARY K233195

1. SUBMITTER'S NAME

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2. ESTABLISHMENT REGISTRATION

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON

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4. DATE PREPARED

September 27, 2023

5. DEVICE NAME/TRADE NAME

Aplio i900, Aplio i800 and Aplio i700 Software V8.1 Diagnostic Ultrasound System

6. COMMON NAME

System, Diagnostic Ultrasound

7. DEVICE CLASSIFICATION

Class II
Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-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 V7.0 (Primary predicate)	Canon Medical Systems USA, Inc.	K223017	March 31, 2023
OLYMPUS GF TYPE UC180, OLYMPUS GF TYPE UCT180 EVIS EXERA II ULATRASOUND GASTROVIDEOSCOPE (Reference device)	Olympus Medical Systems Corporation	K093395	June 17, 2010

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, V8.1 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 33 MHz.

11. INDICATIONS FOR USE

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 is connected, Aplio i800 Model TUS-AI800 /E3 provides image information for diagnosis of the upper gastrointestinal tract and surrounding organs.

12. SUBSTANTIAL EQUIVALENCE

The subject devices, Aplio i900, Aplio i800 and Aplio i700 Software V8.1 Diagnostic Ultrasound System are substantially equivalent to the predicate devices 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 new features, as well as improvements to existing features and functionality. This submission includes details which demonstrate the substantial equivalence of the new and improved features and functionality, to those currently cleared with the predicate devices. Differences between the subject devices and the cleared predicate devices 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 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 with the exception of the addition of transducer model GF-UCT180, manufactured by Olympus Medical Systems Corporation, exclusively for Aplio i800 Model TUS-AI800/E3
    - The indicated uses available with the subject devices are pre-existing with the predicate devices, with the exception of added imaging of upper gastrointestinal tract and surrounding organs, enabled for Aplio i800 Model TUS-AI800/E3 by GF-UCT180
- The software features supported in the subject and predicate devices are identical except for the following new features and improvements to features or functionality available with the predicate devices:
    - Left Atrial Appendage (LAA) Analysis, a new feature which enables the assessment of dimensions for certain user specified parameters, as well as provides a shape model of the left atrial appendage
    - Strain Ratio Measurement, an improvement to existing strain elastography functionality which enables the calculation of strain ratio for strain elastography images
    - Ultra Wideview Support for Mecha4D, an improvement to the existing Wideview feature, enabling its use with Mecha4D transducer model, PVT-675MVS
    - CEUS viewer, an improvement to existing functionality which enables a viewer for stored contrast exam images

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 AAMI/ANSI 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 of these studies demonstrate that the subject devices meet established specifications and perform as intended and in accordance with labeling. The following provides a summary of the testing conducted in support of the new and improved features:

Non-clinical Testing:

Left Atrial Appendage (LAA) Analysis – This study was applied to 10 clinical data sets acquired for the accompanying clinical evaluation of this feature, and demonstrated the ability of LAA Analysis to produce equivalent measurement results as the existing manual measurements.

Strain Ratio Measurement – This study was conducted using elasticity phantoms and demonstrated the ability of Strain Ratio Measurement to calculate strain ratio equivalent to the known elasticity values.

Ultra Wideview for Mech4D – This study demonstrated the capability of the scan range for 4D mode to be increased with Mecha4D transducer model, PVT-675MVS, for which availability of the existing Ultra Wideview feature is expanded.

Olympus EUS Transducer integration – This study demonstrated the successful integration of the cleared Olympus Medical Systems Corporation manufactured EUS transducer model, GF-UCT180, with the Aplio i800 Model TUS-AI800A/E3, V8.1, in accordance with requirements pre-specified by Olympus Medical Systems Corporation.

Clinical Testing:

Left Atrial Appendage (LAA) Analysis – This study, evaluated by a cardiologist and applied to 10 in-vivo cine data, confirmed workflow improvements compared to existing manual workflow in the establishment of a shape model of the left atrial appendage, as well as the ability of LAA Analysis to provide measurement results which are useful for the planning of transcatheter LAAO.

By passing all prespecified performance criteria, it was demonstrated that the new and improved features included in this submission perform equivalently to the predicate device, and as described in labeling.

FDA guidance document “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”, issued February 21, 2023 was referenced for this submission, along with “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023.

Additionally, cybersecurity documentation, per the FDA cybersecurity premarket guidance document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” issued on October 02, 2014, is included in this submission.

Testing of these devices 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, Aplio i800 and Aplio i700 Software V8.1 Diagnostic Ultrasound System 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 the Aplio i900, Aplio i800 and Aplio i700 Software V8.1 Diagnostic Ultrasound System are safe and effective for their intended use, and perform with substantial equivalence to the predicate devices.