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

January 24, 2022

Re: K212333
Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V6.5
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 21, 2021
Received: December 23, 2021

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K212333

Device Name
Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V6.5

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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510(k) SUMMARY K212333

1. SUBMITTER'S NAME

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2. ESTABLISHMENT REGISTRATION

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON

Yoshiaki Cook
Manager, Regulatory Affairs
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Tustin, CA 92780
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4. DATE PREPARED

July 23, 2021

5. DEVICE NAME/TRADE NAME

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V6.5

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 V5.1	Canon Medical Systems USA	K201972	October 08, 2020

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, V6.5 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 30 MHz.

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, V6.5 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V5.1 (K201972). 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 modifications to the cleared predicate devices, to introduce a new feature as well as improve upon existing features. This submission includes details which demonstrate the substantial equivalence of the new and improved features, to those currently cleared with the predicate device.

- The subject Aplio i900/i800/i700, V6.5 and predicate Aplio i900/i800/i700, V5.1 use the same imaging modes and support identical transducers
- The software features supported in the subject Aplio i900/i800/i700, V6.5 and predicate Aplio i900/i800/i700, V5.1 are identical except the following new feature:
    - Tissue Shift Tracking, a new feature which incorporates existing color mapping functionality to visualize calculated parameters

- In addition to this new feature, the following features or functionality available with predicate Aplio i900/i800/i700, V5.1 have been improved in the subject device:
    - Network Storage, an improvement to existing functionality, enabling storage of raw data directly into Network Attached Storage
    - Tricefy Access, an improvement to existing functionality, enabling transfer of DICOM data through firewall to the Tricefy server
    - Attenuation Imaging for Linear, an improvement expanding availability of the existing Attenuation Imaging feature to a linear transducer
    - Dispersion Map for SWE Linear, an improvement expanding availability of the existing Dispersion Map for SWE Linear to a linear transducer
    - Smart Body Mark for Abdomen, an improvement which extends support of existing Smart Body Mark functionality for abdominal use
    - SWE Hard, an improvement to the existing SWE Hard feature, expanding the upper limit and range of shear wave elastography
    - Lung Preset, an improvement to existing preset and body mark functionality by expanding its applicability to lung imaging
    - iBeam+ with Full Focus, an improvement to the existing iBeam+ feature by introduction of the Full Focus capability
    - Apligate and Apligate Soft, an improvement to existing image transfer capability by enabling the ability to share deidentified images
    - Breast Package and Breast Package Soft, an improvement which packages existing features which have utility for breast examinations

- The expansion of marketing language for several previously 510(k) cleared features is also proposed in the subject submission, including the promotion of the support by artificial intelligence (AI) and/or machine learning (ML) of the automated initial contour tracing capability of 2D Wall Motion Tracking for left ventricle (2D WMT) and Auto Ejection Fraction for left ventricle (Auto EF), marketed by Canon as 2D WMT with Full-assist function and Auto EF with Full-assist function, respectively.

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 ES60601-1:2012, IEC 60601-1-2 (2014), IEC 60601-2-37 (2015), IEC 62304 (2015), IEC 62359 (2017) and ISO 10993-1 (2009) standards.

15. TESTING

Risk Analysis and verification and validation activities demonstrate that the established specifications for these devices have been met. Additional performance testing, using phantoms, test data, and volunteer data, were conducted in order to demonstrate that the requirements for the new and improved features were met. The results of all of these studies demonstrate that the new and improved features meet established specifications and perform as intended.

No clinical studies were required to demonstrate safety and efficacy of the Aplio i900/i800/i700, V6.5 systems.

FDA guidance document “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”, issued June 27, 2019 was referenced for this submission, along with “Guidance for

the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005.

Additionally, cybersecurity documentation, per the FDA cybersecurity premarket guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued on October 18, 2018, 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, V6.5 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V5.1, K201972. The subject devices function in a manner similar to and are intended for the same use as the predicate devices, as described in the labeling. Based upon the bench testing, successful completion of software validation, and application of risk management and design controls, it is concluded that these devices are safe and effective for their intended use and perform with substantial equivalence to the predicate devices.