March 31, 2023

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

Re: K223017
Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 27, 2023
Received: March 1, 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 (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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223017

Device Name
Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0

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.

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

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510(k) SUMMARY K223017

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, 2022

5. DEVICE NAME/TRADE NAME

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0

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 V6.5	Canon Medical Systems USA, Inc.	K212333	January 24, 2022

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, V7.0 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 33 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, V7.0 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V6.5 (K212333). 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, including the addition of a new transducer, as well as improve upon existing features and functionality. This submission includes details which demonstrate the substantial equivalence of the improved features, to those currently cleared with the predicate device.

- The subject Aplio i900/i800/i700, V7.0 and predicate Aplio i900/i800/i700, V6.5 have the same clinical intended use and use the same imaging modes, except that Smart3D mode was expanded to now include laparoscopic use
- The transducers supported by the subject and predicate Aplio i900/i800/i700 systems are identical with the exception of the newly available PSI-28VX which shares technological and biocompatibility characteristics with transducers available with the predicate devices,

as well as does not introduce indications for use not previously existing with Aplio i900/i800/i700, V6.5.

- The software features supported in the subject Aplio i900/i800/i700, V7.0 and predicate Aplio i900/i800/i700, V6.5 are identical except for the following improvements to features or functionality available with predicate Aplio i900/i800/i700, V6.5
    - ApliCam kit, which supports the ability to display and store images acquired by a supported USB camera on the ultrasound system screen
    - Contrast Enhance kit, marketed in the U.S. as Clarity, which improves cardiac image quality
    - 2D Wall Motion Tracking, which in the subject submission is improved to support the new clinical target, left atrium
    - Enhanced contrast with Quick Scan by addition of a new setting
    - Expanded availability of Full focus feature, for select non-iBeam+ transducers
    - Attenuation Imaging (ATI), improved by the addition of a filter which excludes abdominal wall multiplex from the attenuation coefficient calculation, as well as the following
        - Support of a trend graph for existing calculations for the Multi-Parametric Report
        - Added “Mini-Worksheet” for real-time display of existing calculations in GUI
    - Ultrasound Scanning Condition Export Function kit, which enables the ability to export images and associated information to a LAN-connected Canon Angiography workstation
    - Triplex improvement for obstetric (OB) imaging, by which a new setting for existing modes is introduced for improved image quality
    - OB 4D image quality improvements related to brightness and smoothness, as well as existing Luminance and Flexible cutline functionality
    - Improvements to TCD image quality, enabling better visibility of structures in B mode and better visibility and sensitivity in CDI mode
    - Support of a higher frequency with transducer model PLI-3003BX
    - Workflow improvements, including
        - Ability of users to enable or disable display of PRF
        - Improved visibility of horizontal scale marker
        - Ability to preview thumbnails of images sent to NAS
        - Improvements to existing Smart body mark functionality, including ability to change its position for abdominal studies, selectable display of probe icon for breast studies, and display of a message informing users when a low quality value is obtained from the position sensor
        - Improvements to existing Smart Fusion feature, including reduction in time to start from 2D mode, support of 2-point/3-point alignment in addition to existing 1-point alignment, and ability to change diameter of the Sphere ROI using the trackball in addition to by the rotary encoder
        - Retention of needle tip position when resuming existing Prostate Biopsy Report function from standby
        - Operational improvements to existing RAD features, including touch command screen (TCS) support of select functionality
        - Improvements to Freeze button and 4D Laser Line functionality of existing Cardiac 4D imaging capability
        - Extension of R-R store range to 20 cycles

- Addition of a formula derived from existing measurement values in user customization tool for Multi-Parametric Report
- Expanded support of existing Smart3D feature by Laparoscopic transducer model PET-805LA
- DICOM support of additional data types, RG(Radiographic Imaging) and RTSTRUCT (RT Structure Set)
- Ability to change TCS font and font size
- Ability to support a new Patient "ID only" registration method
- Additional support of PVA Dur-A Dur(MV) format
- Several improvements to existing OB measurement capabilities, including added support of "%tile" display format for Doppler measurements, and ability to output heartrate from Uterine Artery measurements
- Support of additional Cardiac Doppler manual measurements
- Ability to preset STIC state and Cine playback rate for existing STIC feature
- Addition of several buttons to enable workflow improvements with existing Smart Fetal Heart feature
- Improved DICOM voxel export format resolution
- For 2D Wall Motion Tracking and 3D Wall Motion Tracking, ability to preset auto trace mode, as well as for 2D Wall Motion Tracking, support of auto trace for inverted images and an improvement to SmartFetal2D by which the user no longer must re-set the ROI after pressing "Cycle select"

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 included in the submission was conducted in order to demonstrate that the requirements for the improved features were met. The results of all of these studies demonstrate that the improved features meet established specifications and perform as intended.

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, V7.0 are substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V6.5, K212333. 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, V7.0 are safe and effective for their intended use and perform with substantial equivalence to the predicate devices.