Canon Medical Systems Corporation
% Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

October 8, 2020

Re: K201972
Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V5.1
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 13, 2020
Received: July 15, 2020

Dear Mr. Tadeo:

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)*

K201972

Device Name
Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V5.1

Indications for Use *(Describe)*

The Diagnostic Ultrasound System Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700 is 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

K201972

1. SUBMITTER'S NAME

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-ken, Japan 324-8550

2. OFFICIAL CORRESPONDENT

Fumiaki Teshima

3. ESTABLISHMENT REGISTRATION

9614698

4. CONTACT PERSON

Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

5. Date Prepared

July 13, 2020

6. DEVICE NAME

Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V5.1

7. TRADE NAME(S)

Diagnostic Ultrasound System
Aplio i900 Model TUS-AI900 Software Version V5.1
Aplio i800 Model TUS-AI800 Software Version V5.1
Aplio i700 Model TUS-AI700 Software Version V5.1

8. COMMON NAME

System, Diagnostic Ultrasound

9. 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]

10. PREDICATE DEVICE

Product	Marketed by	510(k) Number	Clearance Date
Aplio i900/i800/i700 Diagnostic Ultrasound System, V4.0 *(Primary Predicate Device)*	Canon Medical Systems USA	K191467	July 19, 2019
Versana Premier *(Reference Predicate Device)*	GE Healthcare	K182277	November 21, 2018
Voluson E10 *(Reference Predicate Device)*	GE Healthcare	K172342	September 29, 2017
AIXPLORER® MACH Ultrasound Diagnostic Systems *(Reference Predicate Device)*	Super Imagine	K180572	May 29, 2018
Epiq 7 *(Reference Predicate Device)*	Philips Medical Systems	K181485	July 27, 2018

11. DEVICE DESCRIPTION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V5.1 are mobile, compact diagnostic ultrasound systems which implement the latest technologies. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 30 MHz.

12. INDICATIONS FOR USE

The Diagnostic Ultrasound System Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700 is 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.

13. SUBSTANTIAL EQUIVALENCE

The purpose of this submission is the modification of the cleared Aplio i900/i800/i700, Diagnostic Ultrasound System, V4.0, K191467, marketed by Canon Medical Systems USA, to which the subject device is substantially equivalent.

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, and Aplio i700 Model TUS-AI700, V5.1 employ the same fundamental scientific technology as the predicate devices, and functions in a manner similar to and is intended for the same use as the predicate devices.

The subject device includes modifications to the cleared device which improves upon existing features. This submission also includes details regarding new features determined to be substantially equivalent to features cleared under the predicate devices referenced within this submission.

- The Aplio i900/i800/i700 and predicate Aplio i900/i800/i700 have the same clinical intended use and the same imaging modes, except that Thoracic/Pleural is now available on several transducers on the subject Aplio i900/i800/i700, and Shear Wave Elastography mode was expanded to include musculo-skeletal clinical use.
- The transducers supported in the subject Aplio i900/i800/i700 and predicate Aplio i900/i800/i700 are identical except the addition of new transducer PLI-605BX which shares the same fundamental technological and biocompatibility characteristics as existing transducers supported by the predicate Aplio i900/i800/i700.
- The software features supported in subject Aplio i900/i800/i700 and predicate Aplio i900/i800/i700 are identical except the following main, new features:
    - Smart Fetal Heart, a new feature which improves upon existing manual workflow to acquire fetal heart views, available on predicate Aplio i900/i800/i700.
    - LI-RADS Checklist, a new feature predicated upon existing features available on predicate Aplio i900/i800/i700, which supports the standardization of liver characterization based on American College of Radiology, (ACR) guidelines.
    - Fluctuational imaging, a new feature similar to functionality available with Attenuation Imaging, a feature available on predicate Aplio i900/i800/i700, which displays the degree of fluctuation in tissue.
    - Workflow Navigator, a new feature predicated on existing workflow functionality available on predicate Aplio i900/i800/i700 which provides workflow and reporting support based on American Society of Echocardiography, (ASE) guidelines for specific medical conditions.
    - Smart Optimization, a new feature similar to “Whizz” on the Versana Premier by GE Healthcare (K182277) which is intended to improve image quality targeting the abdominal region.
    - Prostate Biopsy Report, a new feature which adds functionality existing in predicate Aplio i900/i800/i700, to provide a workflow panel for biopsy procedures and 3D modeling for visualization during these procedures.
- In addition to these new features, several existing features available with predicate Aplio i900/i800/i700 (K191467) have been modified for improved functionality in the subject device:
    - Smart Body Mark, an improvement to manual breast scan workflow by incorporation of previously cleared functionality
    - MSK Protocol movie, to support the display of musculo-skeletal (MSK) instructional movies with existing functionality
    - Wide View support, an expansion of the scan range available with convex transducers
    - iBeam+, an improvement to conventional iBeam by increased processing speed

- SMI G4, an improvement to the previous generation of SMI by enhanced clutter suppression, supported by the availability of a higher detection range
- Sensor 3D, modified to support improved resolution
- Obstetric Image quality, modified to support improved visualization
- Cardiac 4D Luminance, an improvement to conventional Luminance by migration of a previously cleared feature

14. SAFETY

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is 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, Verification/Validation testing conducted through bench testing and clinical evaluation which are included in this submission demonstrates that the requirements for the new and improved features have been met. Additional performance testing, using test data and volunteer studies, were conducted to assess improvements to existing features. Results of all these studies demonstrated that the improvements met specifications are performed as intended.

FDA guidance document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducer", issued June 27, 2019 was referenced for this submission, along with Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005.

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 also referenced for this submission.

Additionally, 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, V5.1 is substantially equivalent to the predicate devices. The subject devices function in a manner similar to and is intended for the same use as the predicate devices, as described in the labeling. Based upon the bench testing, clinical evaluation, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use and performance is substantially equivalent to the predicate devices.