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

October 16, 2020

Re: K202737
Trade/Device Name: Aplio i900/i800/i700/i600 Diagnostic Ultrasound System, Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System, Xario200G and Xario100G, 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: September 15, 2020
Received: September 18, 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 and Part 809); 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)*
K202737

Device Name
Aplio i900/i800/i700/i600 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Diagnostic Ultrasound Systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600 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, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*

K202737

Device Name

Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System

Indications for Use *(Describe)*

The Diagnostic Ultrasound Systems Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450, and Aplio a Model CUS-AA000 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, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

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)

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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)*

K202737

Device Name
Xario200G and Xario100G, Diagnostic Ultrasound System

Indications for Use *(Describe)*

The Diagnostic Ultrasound System Xario200G Model CUS-X200G and Xario100G Model CUS-X100G 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), laparoscopic, pediatric, small organs, neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric, trans-esoph(cardiac) and peripheral vessel.

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

1. SUBMITTER'S NAME

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Otawara-shi, Tochigi-ken, Japan 324-8550

2. OFFICIAL CORRESPONDENT

Fumiaki Teshima
Sr. Manager, Quality Assurance Department

3. ESTABLISHMENT REGISTRATION

9614698

4. CONTACT PERSON

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

5. DATE PREPARED

September 15, 2020

6. DEVICE NAME(S)

Aplio i900/i800/i700/i600 Diagnostic Ultrasound System
Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System
Xario200G and Xario100G, Diagnostic Ultrasound System

7. TRADE NAME(S)

Diagnostic Ultrasound System
Aplio i900 Model TUS-AI900
Aplio i800 Model TUS-AI800
Aplio i700 Model TUS-AI700
Aplio i600 Model TUS-AI600

Aplio a550 Model CUS-AA550
Aplio a450 Model CUS-AA450
Aplio a Model CUS-AA000

Xario200G Model CUS-X200G
Xario100G Model CUS-X100G

8. COMMON NAME

Diagnostic Ultrasound System and Transducers

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/i600 Diagnostic Ultrasound System, V4.0	Canon Medical Systems USA	K191467	July 19, 2019
Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System, V4.0	Canon Medical Systems USA	K191663	September 18, 2019
Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System	Canon Medical Systems USA	K182596	November 02, 2018

11. REASON FOR SUBMISSION

Modification of labeling for a cleared device.

12. DEVICE DESCRIPTION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600 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.

The Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450 and Aplio a Model CUS-AA000 are mobile diagnostic ultrasound systems. 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 20 MHz.

The Xario200G Model CUS-X200G and Xario100G Model CUS-X100G are mobile diagnostic ultrasound systems. 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 12 MHz.

13. INDICATIONS FOR USE

Aplio i900/i800/i700/i600 Diagnostic Ultrasound System

The Diagnostic Ultrasound Systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600 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, trans-vaginal, trans-rectal, neonatal cephalic,

adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System
The Diagnostic Ultrasound Systems Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450, and Aplio a Model CUS-AA000 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, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

Xario200G and Xario100G, Diagnostic Ultrasound System
The Diagnostic Ultrasound System Xario200G Model CUS-X200G and Xario100G Model CUS-X100G 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), laparoscopic, pediatric, small organs, neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric, trans-esoph(cardiac) and peripheral vessel.

14. SUBSTANTIAL EQUIVALENCE

The purpose of this submission is the modification of the labeling for **Aplio i900/i800/i700/i600 Diagnostic Ultrasound System, V4.0, K191467**; **Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System, V4.0, K191663**; and **Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System, K182596**, marketed by Canon Medical Systems USA, to which the subject devices are substantially equivalent.
The subject devices, **Aplio i900/i800/i700/i600 Diagnostic Ultrasound System**; **Aplio a550, Aplio a450, and Aplio a, Diagnostic Ultrasound System**; and **Xario200G and Xario100G, Diagnostic Ultrasound System**, each employ the same fundamental scientific technology as their respective predicate device, and function in the same manner and are intended for the same use as their respective predicate device.

This submission includes a modification to the cleared devices to expand labeling for lung and cardiac imaging functionality. The subject devices are otherwise unchanged from their respective predicate device, and are determined to be substantially equivalent.

- The subject devices and their respective predicate employ the same operating principle and have the same imaging modes.
- The transducers supported in the subject devices and their respective predicate are identical, and share the same fundamental technological and biocompatibility characteristics.
- The software features supported in the subject devices and their respective predicate device are identical.
- The hardware components of the subject devices and their respective predicate device are identical.

15. TESTING

Performance data is not required for this submission. Design control measures are discussed within the submission.

16. CONCLUSION

The major change to the devices is to expand the labeling to include information about lung and cardiac imaging, based upon societal guidelines, for patients who have been diagnosed with the novel coronavirus disease 2019 (COVID-19). This labeling update is being provided without changes to the software, hardware and intended use of the subject devices. This labeling change did not impact the previous design controls for the subject devices.