November 21, 2023

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

Re: K232988
Trade/Device Name: Aplio flex and Aplio go Software V2.0 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 21, 2023
Received: September 22, 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, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*

K232988

Device Name
Aplio flex and Aplio go Software V2.0 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Diagnostic Ultrasound System Aplio flex Model CUS-AFL00 and Aplio go Model CUS-AGG00 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, pediatric, small organ (thyroid, breast and testicle), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculoskeletal (both conventional and superficial), cardiac, peripheral vascular, 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 as well as Tissue Harmonic Imaging, Combined Modes 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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K232988

510(k) SUMMARY

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 21, 2023

5. **DEVICE NAME/TRADE NAME**

Aplio flex and Aplio go Software V2.0 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
Xario 200G/100G Diagnostic Ultrasound System, Software Version 1.1 (Primary predicate)	Canon Medical Systems USA, Inc.	K182596	November 02, 2018
Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0 (Reference device)	Canon Medical Systems USA, Inc.	K223017	March 31, 2023

9. REASON FOR SUBMISSION

New device.

10. DEVICE DESCRIPTION

The Aplio flex, Model CUS-AFL00 and Aplio go, Model CUS-AGG00, V2.0 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ an array of probes including flat linear array, convex, and sector array with frequency ranges between approximately 2.5MHz to 12MHz.

11. INDICATIONS FOR USE

The Diagnostic Ultrasound System Aplio flex Model CUS-AFL00 and Aplio go Model CUS-AGG00 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, pediatric, small organ (thyroid, breast and testicle), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculoskeletal (both conventional and superficial), cardiac, peripheral vascular, 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 as well as Tissue Harmonic Imaging, Combined Modes 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 subject devices, Aplio flex and Aplio go Software V2.0 Diagnostic Ultrasound System, are substantially equivalent to the predicate devices, Xario 200G/100G Diagnostic Ultrasound System, Software Version 1.1 (K182596).

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. 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 and predicate devices have the same clinical intended use and imaging modes, which differ only by the availability of Pencil Scan and CW Pencil Mode with the predicate devices
    - The indicated uses available with the subject devices are pre-existing with the predicate devices, with the exception of the additional availability of thoracic/pleural imaging with the subject devices
- The transducers newly developed for use with the subject devices employ the same fundamental scientific technology and are substantially equivalent to those existing with the predicate devices, while the remaining transducers supported by the subject devices have been previously cleared with the predicate devices
- The software features supported in the subject and predicate devices are largely identical.
    - The following features, previously cleared with reference devices, Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0 (K223017), and which are implemented into the subject devices, are not available with the predicate devices:
        - Attenuation Imaging, which enables the calculation and visualization of the ultrasound frequency dependent attenuation coefficient
        - Vascularity Index, which provides measurements based upon the calculation of pixels within a Power image
        - Lateral Gain, which enables the ability to adjust gain control from image edge to edge
        - ApliGate, which enables sharing of de-identified images from Aplio flex and Aplio go
        - Network Storage, which enables raw data to be stored to a Network Attached Server (NAS)
        - Tricefy Access, which enables DICOM images to be sent from Aplio flex and Aplio go through a firewall to the Tricefy cloud server, a Class 1 medical device
    - The following features and/or functionality, previously cleared with the predicate devices, are improved in the subject devices as follows:
        - Trapezoid scan is now enabled for B mode and tilted scan for CDI, PDI, and ADF
        - QuickScan now enables the setting of PWD gate within the ROI, as well as Doppler angle correction marker and angle oblique scan, in relation to flow location and direction
        - Mecha4D now enables OmniView image, a display of the transverse plane, along the cutline set on an MPR image
        - Luminance now supports transducer model PVU-674MVS
        - Protocol Assistant now enables any cine/still image to be displayed as a guide, previously acquired examination images to be displayed as reference, and any user input text to be displayed
        - Capability to hold an additional transducer, now up to a total of four
    - The following features and/or functionality, which are available with the predicate devices, are not implemented into the Aplio flex and Aplio go
        - Superb Micro vascular Imaging (SMI); other Color Doppler image processing features are equivalent between the subject and predicate devices
        - Auto IMT, a vascular measurement feature; other application measurements are identical between the subject and predicate devices

- 2D Wall Motion Tracking, which enables myocardial wall motion analysis by regional pattern matching in 2D cardiac images
- Contrast Imaging, Stress Echo, Shear Wave, and Elastography

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 features 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.

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 flex, Model CUS-AFL00 and Aplio go, Model CUS-AGG00, V2.0 are substantially equivalent to the Xario 200G/100G Diagnostic Ultrasound System, Software Version 1.1, K182596. 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 flex, Model CUS-AFL00 and Aplio go, Model CUS-AGG00, V2.0 are safe and effective for their intended use and perform with substantial equivalence to the predicate devices.