April 30, 2025

Canon Medical Systems Corporation
% Yoshiaki Cook
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, California 92780

Re: K250328
Trade/Device Name: UltraExtend NX CUW-U001S V2.0 Ultrasound Image Analysis Program
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, IYN, IYO
Dated: February 5, 2025
Received: February 5, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250328

Device Name

UltraExtend NX CUW-U001S V2.0 Ultrasound Image Analysis Program

Indications for Use *(Describe)*

UltraExtend NX CUW-U001S Ultrasound Image Analysis Program is designed to allow the user to observe images and perform analysis based on examination data acquired using the following diagnostic ultrasound systems; TUS-AI900, TUS-AI800, and TUS-AI700.

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.

510(k) SUMMARY

1. SUBMITTER'S NAME

Fumiaki Teshima
Sr. Manager, Quality Assurance Dept.
Quality, Safety and Regulation Center
Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-ken, Japan 324-8550

2. ESTABLISHMENT REGISTRATION

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON

Yoshiaki Cook
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, CA 92780
ycook@us.medical.canon
+1 (657) 270-5595

4. DATE PREPARED

February 05, 2025

5. DEVICE NAME/TRADE NAME

UltraExtend NX CUW-U001S V2.0 Ultrasound Image Analysis Program

6. COMMON NAME

Radiological Image Processing System

7. DEVICE CLASSIFICATION

Class II
Medical Image Management and Processing System – Product Code: QIH [per 21 CFR892.2050]
Subsequent Product Codes:
Ultrasonic Pulsed Doppler Imaging System – Product Code: IYN [per 21 CFR 892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: IYO [per 21 CFR 892.1560]

8. PREDICATE DEVICE

Product	Marketed by	Regulation Number & Classification Product Code	510(k) Number	Clearance Date
UltraExtend FX, Ultrasound Workstation Package, V2.02 (Primary predicate device)	Canon Medical Systems USA, Inc.	892.2050 LLZ	K121076	10/09/2012
Aplio i900/i800/i700 Diagnostic Ultrasound System, Software Version 7.0 (Reference device)	Canon Medical Systems USA, Inc.	892.1550 IYN	K223017	03/31/2023

9. REASON FOR SUBMISSION

Introduction of a new device.

10. DEVICE DESCRIPTION

The UltraExtend NX, V2.0 is designed to allow the user to observe images and perform analysis based on examination data acquired using the Aplio i900/i800/i700 diagnostic ultrasound systems. RAW only or data saved in Image + RAW should be used for UltraExtend NX.

11. INDICATIONS FOR USE

UltraExtend NX CUW-U001S Ultrasound Image Analysis Program is designed to allow the user to observe images and perform analysis based on examination data acquired using the following diagnostic ultrasound systems; TUS-AI900, TUS-AI800, and TUS-AI700.

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 UltraExtend NX, V2.0 is substantially equivalent to the UltraExtend FX, V2.02 (K121076). The subject device employs the same fundamental scientific technology as the primary predicate device and functions in a manner similar to, and is intended for the same use as the primary predicate device. The subject device differs from the primary predicate device primarily by the latter's compatibility with image data acquired by the Aplio 300, 400, and 500 Ultrasound system models, and several software features and improvements to software functionality cleared in the reference device (K223017), which are not implemented in the primary predicate device. These differences do not raise any new questions about the safety and effectiveness of the subject device, and evidence is provided in this submission to demonstrate the substantial equivalence of the subject and predicate devices.

- The subject device has the same clinical intended use as the predicate device, and both are application software products enabling post processing of image data acquired by compatible Ultrasound system models

- The software features and functionality supported in the subject and primary predicate devices are identical except for the following features and improvements to software functionality which are available with the reference device, but not implemented in the primary predicate device
    - Availability of certain measurement packages (Standard measurements, Application measurements, Obstetrics measurements) which are not available, or limited in the primary predicate device
    - Availability of capabilities with the Cardiac4D feature which are limited in the primary predicate device
    - 2D Wall Motion Tracking, which is expanded to include left atrial analysis and the AI/ML-enabled Full-assist function for left ventricle, both of which are not available with the primary predicate device
    - Auto EF LV, including with the AI/ML-enabled Full-assist function for the left ventricle, which are not available with the primary predicate device
    - 3D Wall Motion Tracking, Aortic Valve Analysis, Smart Fetal Heart, Flex-M, and Vascularity Index features which are not available with the primary predicate device

13. SAFETY

The subject 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 IEC 62304 Edition 1.1 2015-06 and IEC 62366-1 Edition 1.1 2020-06 standards.

14. TESTING

Risk Analysis and verification and validation activities demonstrate that the established specifications for these devices have been met. Additional performance testing was conducted in order to demonstrate that the requirements for the features and software functionality were met. The results of this testing demonstrate that the subject device meets established specifications and performs as intended and in accordance with labeling.

Software documentation appropriate for the Basic Documentation Level, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, was included in this submission.

Additionally, cybersecurity documentation, per the FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", issued on September 27, 2023, was included in this submission.

PERFORMANCE TESTING OF AI/ML-BASED FUNCTIONALITY MIGRATED FROM REFERENCE DEVICE (K223017)

In this submission, 2D Wall Motion Tracking with Full-assist function for left ventricle (LV) and Auto EF with Full-assist function for LV, as cleared with the reference device, were both integrated without modification into UltraExtend NX, V2.0.

In order to demonstrate that when integrated into the subject device, both features perform with substantial equivalence as with the reference device, these studies utilized a representative subset of the clinical data acquired for the original performance testing of these features; additionally these studies applied the same acceptance criteria to evaluate the performance of these features compared to the same ground truth as utilized in the original performance evaluation of these features with the reference device.

The results of this testing demonstrate that both features perform as intended when integrated into the subject device, and with substantial equivalence as with the reference device. Appropriate instructions for use and performance information related to the AI/ML-enabled functionality are included in user labeling as included in this submission.

15. CONCLUSION

UltraExtend NX CUW-U001S V2.0 Ultrasound Image Analysis Program functions in a manner similar to, and is intended for the same use as the UltraExtend FX, Ultrasound Workstation Package, as described in labeling. Based upon the evidence presented in this submission, it is concluded that the subject device has demonstrated substantial equivalence to the predicate devices, and is as safe and effective for its intended use.