Edgecare Inc.
Beom Ki Cha
RA Senior Manager
12F, 8 Yangpyeong-ro 25-gil
Yeongdeungpo-gu, Seoul 07207
SOUTH KOREA

April 17, 2026

Re: K252237
Trade/Device Name: EdgeFlow UW20
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX, QIH
Dated: July 17, 2025
Received: March 19, 2026

Dear Beom Ki Cha:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.04.17 15:58:35 -04'00' For

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252237

Device Name
EdgeFlow UW20

Indications for Use *(Describe)*
The EdgeFlow UW20 is a wearable ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively in adult patients with BMI up to 30. The bladder volume measurements can be performed periodically at a set time interval set by the user. It is intended for use in professional healthcare facilities, such as hospitals and clinics, by qualified and trained healthcare professionals. The EdgeFlow UW20 supports B-mode and harmonic imaging modes.

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

(K252237)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April 16, 2026

1. Information

1.1 Submitter Information

Submitter Name: Edgecare Inc.

Address: 12F, 8 Yangpyeong-ro 25-gil, Yeongdeungpo-gu, Seoul, 07207, Korea, South

Telephone: +82-10-6229-0668

Website: www.edgecare.co.kr

1.2 Official Correspondent

Name: Beom Ki Cha

Address: 12F, 8 Yangpyeong-ro 25-gil, Yeongdeungpo-gu, Seoul, 07207, Korea, South

E-mail: beomki.cha@edgecare.kr

U.S. Agent: KMC USA Inc., R5450 Astor Lane #203, Rolling Mdws, IL 60008, U.S.A.

2. Device Information

2.1 Trade Name / Proprietary Name: EdgeFlow UW20

2.2 Common Name: Ultrasonic Pulsed Echo Imaging System

2.3 Classification Name: Ultrasonic pulsed echo imaging system

2.4 Product Code: IYO, ITX, QIH

2.5 Classification Regulation: 21 CFR 892.1560, 21 CFR 892.1570, 21 CFR 892.2050

2.6 Device Class: Class II

2.7 Classification Panel: Radiology

3. Predicate Device

- Primary Predicate Device: EdgeFlow UH10 (K231677), Edgecare Inc.
- Reference Device: CUBEScan BioCon-900 (K171591), Mcube Technology Co., Ltd.

4. Subject Device Description

The EdgeFlow UW20 is a wearable ultrasound device designed to non-invasively measure urinary bladder volume during periodic monitoring in adult patients with BMI up to 30. The device consists of a compact ultrasound patch, a designated silicone gel pad supplied by Edgecare Inc., probe integrated electronics, signal transmission electronics, power management circuitry, and a Bluetooth Low Energy (BLE) communication module.

When attached to the lower abdominal skin using the designated gel pad and fixation tape, the EdgeFlow UW20 intermittently activates its embedded transducer array to acquire B-mode ultrasound images of the bladder. Measurements are performed automatically at user-defined time intervals, minimizing operator intervention while maintaining consistent image acquisition quality in the intended clinical environment.

Captured ultrasound data are transmitted to the EdgeFlow_UW20 mobile application, which functions as the user interface, data management system, and image review platform. A pre-trained deep learning algorithm embedded within the application performs automated bladder segmentation and volume estimation based on the received ultrasound images. The algorithm operates in a locked, non-learning mode to ensure consistent and reproducible performance across all measurement sessions.

Unlike conventional handheld bladder scanners, the EdgeFlow UW20 is designed for wearable intermittent monitoring in professional healthcare facilities. The wearable design enables periodic bladder volume assessment over an extended monitoring interval without requiring repeated manual scanning at each measurement time point.

5. Indications for Use

The EdgeFlow UW20 is a wearable ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively in adult patients with BMI up to 30. The bladder volume measurements can be performed periodically at a set time interval set by the user. It is intended for use in professional healthcare facilities, such as hospitals and clinics, by qualified and trained healthcare professionals. The EdgeFlow UW20 supports B-mode and harmonic imaging modes.

CAUTION – Limitations: The EdgeFlow UW20 is indicated for use in adult patients with BMI up to 30 kg/m^2. The effectiveness of this device in patients with BMI greater than 30 kg/m^2 have not been established. Use of this device in patients outside the indicated BMI range is not recommended.

6. Substantial Equivalence

Comparison of the technical characteristics of the subject device and predicate devices is shown in the table below.

Characteristic	**Subject Device (UW20)**	**Primary Predicate (K231677)**	**Reference Device (K171591)**
Manufacturer	Edgecare Inc.	Edgecare Inc.	Mcube Technology Co., Ltd.
Trade Name	EdgeFlow UW20	EdgeFlow UH10	CUBEScan BioCon-900
510(k) Number	-	K231677	K171591
Product Code	IYO, ITX, QIH	IYO, ITX, QIH	IYO, ITX
Indications for Use	Wearable ultrasound device for noninvasive bladder volume measurement in adult patients (BMI up to 30) by qualified HCPs in professional healthcare facilities	Ultrasound device for noninvasive bladder volume measurement by qualified HCPs in professional healthcare facilities	B-mode pulsed-echo ultrasound device for noninvasive bladder volume measurement by qualified medical professionals
Contraindications	Lower abdominal wounds/sutures/incisions, excessive lower abdominal obesity, pregnant women,	Fetal use, pregnant patients, allergic to coupling agents, abdominal wound/skin disease	Fetal use, pregnant patients, ascites, open wounds in suprapubic region

Characteristic	Subject Device (UW20)	Primary Predicate (K231677)	Reference Device (K171591)
	patients under 18 years		
Intended User	Qualified and trained healthcare professionals (physicians, nurses)	Physicians/Medical Professionals	Physicians/Medical Professionals
Target Population	Adults ≥18 years, BMI ≤30 kg/m^2	Male, Female, Pediatric	Male, Female
Anatomical Site	Bladder	Bladder	Bladder
Appearance	Wearable (patch)	Handheld	Handheld
Technology	Neural network (deep learning)	Neural network (deep learning)	Neural network technology
Sterility	Non-sterile	Non-sterile	Non-sterile
Power Source	Battery Powered (Lithium-ion)	Battery Powered (Lithium-ion)	Battery Powered (Lithium-ion)
Energy Delivered	Ultrasound	Ultrasound	Ultrasound
Measurement Accuracy	0-100 mL: ±20 mL 101-999 mL: ±15%	0-100 mL: ±7.5 mL 100-999 mL: ±7.5%	±15% or ±15 mL
Measurement Range	0-999 mL	0-999 mL	0-999 mL
2D/3D Image	2D	2D	2D
Mode of Operation	B-mode, Harmonic	B-mode, Harmonic	B-mode
Transducer Type	Electronic Sector Scanning (Phased Array)	Electronic Sector Scanning (Phased Array)	Mechanical Sector Probe
Sector Angle	120 degrees	120 degrees	120 degrees
Number of Scan Planes	1	2	12
Wireless	Bluetooth Low Energy (BLE), Wi-Fi	Wi-Fi	None
FDA Ultrasound Track	Track 3	Track 3	Track 1
Biocompatibility	ISO 10993-5, 10, 23	ISO 10993-5, 10, 23	ISO 10993-5, 10

Comment on Appearance (Wearable vs. Handheld):

The EdgeFlow UW20 differs from the primary predicate in form factor in that it is a wearable patch device rather than a handheld scanner. The device is attached to the lower abdominal skin using the designated EdgeFlow Gel Pad and fixation tape, and its wearable design was specifically evaluated through in-vivo testing demonstrating stable acoustic coupling over the intended 24-hour wear period. The biological safety of all patient-contacting components has been demonstrated through testing in accordance with ISO 10993-1.

Comment on Measurement Accuracy:

The EdgeFlow UW20 has different measurement accuracy specifications from the primary predicate due to its wearable design and intended use as a periodic monitoring device. For volumes from 0 to 100 mL, the predefined acceptance criterion is ±20 mL, and for volumes from 101 to 999 mL, the predefined acceptance criterion is ±15%. Bench testing demonstrated actual deviations substantially smaller than these predefined criteria, including 1.9 mL at 30 mL, 3.4 mL at 50 mL, 4.0 mL at 100 mL, 2.24% at 500 mL, and 1.88% at an upper-range phantom condition. In addition, AI-enabled software validation met all predefined acceptance criteria, including a volume MAE of 14.43 mL for 0–100 mL and a volume MAPE of 10.71% for 101–999 mL. These results support that the difference in the predefined specification does not adversely affect the safety or effectiveness of the device for its intended use.

Comment on Number of Scan Planes:

Although the number of scan planes differs from the predicate devices, the EdgeFlow UW20 uses a different system architecture and locked AI-enabled image analysis algorithm to estimate bladder volume. Performance testing demonstrated that the device met all predefined acceptance criteria for bladder volume measurement; therefore, this technological difference does not raise new questions of safety or effectiveness.

The subject device is substantially equivalent to the primary predicate device (K231677) with respect to intended use, technological characteristics, and overall performance. The identified differences, including wearable form factor, number of scan planes, and predefined accuracy specifications, were addressed through bench, software, biocompatibility, electrical safety, EMC, wireless, and in-vivo performance testing and do not raise new questions of safety or effectiveness.

7. Non-clinical and Clinical Performance Data

The EdgeFlow UW20 underwent performance testing to support the safety and effectiveness of the device, including bench performance testing, acoustic output testing, electrical safety testing, EMC testing, wireless coexistence testing, radio testing, software verification and validation and cybersecurity, biocompatibility evaluation, in-vivo wearable performance testing, and AI-enabled software performance validation. These testing activities were designed to confirm that the device performs as intended under representative use conditions and meets applicable safety and performance requirements for its intended use as a wearable bladder volume measurement device.

Bench Performance Testing

Bench testing was performed using bladder phantoms representing nominal volumes of 30, 50, 100, 500, and 1000 mL. The EdgeFlow UW20 met its predefined acceptance criteria of ±20 mL for 0–100 mL and ±15% for 101–999 mL at all evaluated test conditions, supporting acceptable bladder volume measurement performance across the intended measurement range.

Acoustic Output Testing

Acoustic output testing was performed in accordance with IEC 60601-2-37:2007+AMD1:2015 (Track 3). The maximum Mechanical Index was 0.58, the Thermal Index was 0.17, and the focal depth was 7.5 cm in harmonic mode. These results support that the ultrasound output remains within accepted safety limits for the intended use.

Electrical Safety Testing

Electrical safety testing was performed in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020, AAMI ES60601-1, and applicable national differences. The EdgeFlow UW20 met applicable electrical safety requirements.

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility testing was performed in accordance with IEC 60601-1-2:2014+AMD1:2020 and EN 60601-1-2:2015/A1:2021. The EdgeFlow UW20 met applicable EMC requirements and maintained essential performance under the evaluated test conditions.

Wireless Coexistence and Radio Testing

Wireless coexistence testing was performed in accordance with ANSI C63.27-2017. Radio testing was performed for BLE and Wi-Fi operation in accordance with ETSI EN 300 328 V2.2.2 and FCC Part 15. The device met applicable wireless and radio requirements.

Biocompatibility

Biocompatibility evaluation was performed for all patient-contacting components in accordance with ISO 10993-1:2018. The evaluation included the following tests: cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), and irritation (ISO 10993-23:2021). No biocompatibility concerns were identified.

In-Vivo Wearable Performance Testing

A prospective, single-center in-vivo study was conducted at Severance Hospital to evaluate acoustic coupling stability during 24-hour wearable use of the EdgeFlow UW20. The device was applied and managed by qualified healthcare professionals who were instructed on the study procedures prior to study conduct.

Defined user tasks in the study included device attachment, confirmation of proper positioning and acoustic coupling, initiation of monitoring, review of acquired ultrasound images and bladder volume results, and response to invalid or missing measurements, including repositioning or reattachment when needed. These tasks were successfully performed by qualified healthcare professionals under representative clinical use conditions.

Acquired ultrasound images were reviewed by trained expert annotators to assess whether valid acoustic coupling was maintained. Out of 1,454 ultrasound images acquired, 1,414 maintained valid acoustic coupling, corresponding to an overall coupling retention ratio of 97.24%, which exceeded the predefined acceptance criterion of 80%. No adverse events or early device removals were reported. These results support that the wearable design of the EdgeFlow UW20 can maintain stable acoustic coupling during the intended 24-hour use period in the clinical environment.

AI-Enabled Software Performance

The EdgeFlow UW20 incorporates locked AI-enabled software that performs bladder presence classification, bladder region segmentation, and bladder volume estimation. The software operates in a locked, non-learning mode and does not perform on-device learning, online adaptation, or autonomous post-deployment updating.

Validation data were acquired at Severance Hospital under Institutional Review Board-approved protocols using two source cohorts collected under distinct imaging environments and acquisition systems. Data Source 1 (DS1) consisted of 254 unique subjects acquired in an operating room setting using the UH10 acquisition system (IRB No. 1-2022-0076), and Data Source 2 (DS2) consisted of 32 unique subjects acquired in an inpatient ward setting aligned with the intended use of the device using the UW20 acquisition system (IRB No. 1-2025-0025). For bladder presence classification and bladder segmentation, subject-independent development and held-out testing were performed using DS1-derived analysis-ready datasets comprising 16,349 training images from 197 subjects and 3,710 test images from 57 subjects.

For bladder volume estimation, the development dataset comprised 9,908 training images from 254 DS1 subjects, and the independent held-out test dataset comprised 1,902 test images from 32 DS2 subjects. Because multiple ultrasound images were collected per subject, the number of images exceeded the number of individual subjects; all reported model performance results were derived from image-level analyses, with subject-level separation maintained between development and test datasets to prevent information leakage. The development and test datasets included adult male and female subjects across multiple age and BMI categories. In the segmentation/classification training and test cohorts, male subjects accounted for 64.5% and 49.1%, respectively, and female

subjects accounted for 35.5% and 50.9%, respectively. In the volume-estimation training and test cohorts, male subjects accounted for 61.0% and 62.5%, respectively, and female subjects accounted for 39.0% and 37.5%, respectively. Age distributions across the datasets included subjects younger than 50 years, 50–70 years, and 70 years or older, and BMI distributions included subjects with BMI <25, 25–29.9, and ≥30 kg/m^2.

Prespecified subgroup analyses across sex, age, and BMI showed no evidence of systematic performance degradation in the evaluated subgroups. Dataset independence was maintained through subject-independent partitioning for the segmentation/classification task, complete sequestration of the DS2 cohort for independent volume-model testing, and use of augmentation only in development datasets.

Reference standards were predefined for each software function and were established by qualified clinical personnel independent from model development. For bladder presence classification, two blinded clinical labelers independently assigned a binary present/absent label for each image, and disagreements were adjudicated by an independent evaluator.

For bladder segmentation, two blinded clinical labelers independently generated pixel-level binary masks for each image; when the inter-labeler intersection-over-union (IoU) was 0.90 or greater, a consensus intersection mask was used, and when the IoU was less than 0.90, discrepant cases were adjudicated by an independent evaluator. For volume estimation, the reference standard was the catheter-derived bladder volume recorded at the time of image acquisition and subject to quality-control review.

For each software function, the locked model outputs were compared against these predefined reference standards on held-out test datasets, and performance was evaluated using prespecified endpoints and acceptance criteria with 95% confidence intervals.

For bladder presence classification, the confusion matrix was TP = 2,751, FP = 72, FN = 69, and TN = 818, corresponding to sensitivity of 0.976 and specificity of 0.919. Ninety-five percent confidence intervals were derived using non-parametric percentile bootstrap resampling at the image/frame level (B = 2,000).

Overall Validation Results

Function	Metric	Result (95% CI)	Acceptance Criterion
Bladder presence classification	F1 Score	0.975 (0.972–0.978)	≥0.90
Bladder segmentation	Dice Score	0.936 (0.931–0.940)	≥0.80
Volume estimation (0–100 mL)	MAE	14.43 mL (10.62–18.26)	≤20 mL
Volume estimation (101–999 mL)	MAPE	10.71% (7.49–13.91)	≤15%

Subgroup Performance Summary Across Sex, Age, and BMI

Subgroup Category	Subgroup	Test Subjects		F1	Sensitivity	Specificity	Dice	MAE (0–100 mL)	MAPE (101–999 mL)
		Seg/ Cls	Vol						
Sex	Male	28	20	0.976	0.977	0.920	0.934	14.73 mL	10.92%
	Female	29	12	0.973	0.973	0.917	0.938	13.98 mL	10.41%
Age	<50	16	10	0.975	0.977	0.917	0.933	13.87 mL	10.28%
	50–70	32	18	0.977	0.977	0.920	0.937	14.39 mL	10.68%
	≥70	9	4	0.968	0.968	0.923	0.935	15.12 mL	11.23%
BMI	<25	28	19	0.977	0.979	0.918	0.936	14.06 mL	10.36%
	25–29.9	21	6	0.976	0.976	0.923	0.935	14.52 mL	10.83%
	≥30	8	7	0.967	0.968	0.913	0.933	15.27 mL	11.47%

Taken together, these non-clinical software validation results demonstrate that the AI-enabled software functions of EdgeFlow UW20 performed as intended under the evaluated conditions of use and support the conclusion that the subject device is substantially equivalent to the predicate device.

8. Conclusion

The comparison between the EdgeFlow UW20 and the primary predicate device (K231677, EdgeFlow UH10) demonstrates that the devices have the same overall intended use and similar technological characteristics for noninvasive bladder volume measurement. Both devices are intended for use by qualified healthcare professionals in professional healthcare facilities and are designed to measure urinary bladder volume using ultrasound-based image acquisition and automated analysis.

Based on the intended use, technological characteristics, and performance data provided, the EdgeFlow UW20 is substantially equivalent to the legally marketed predicate device, EdgeFlow UH10 (K231677).