Edgecare Inc.
% Milly
Regulatory Affairs Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
SOUTH KOREA

March 6, 2024

Re: K231677
Trade/Device Name: EdgeFlow UH10
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX, QIH
Dated: February 6, 2024
Received: February 7, 2024

Dear Milly:

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)*
K231677

Device Name
EdgeFlow UH10

Indications for Use *(Describe)*
The EdgeFlow UH10 is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively. It is intended for use in professional healthcare facilities, such as hospitals, clinics, by qualified and trained healthcare professionals. The EdgeFlow UH10 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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
(K231677)

K231677

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

Date: Feb 29, 2024

1. INFORMATION

1.1 Submitter Information

- Submitter Name: Edgecare Inc.
- Address : 403, Teihard Hall, 35, Baekbeom-ro, Mapo-gu, Seoul, 04107, Republic of Korea
- Telephone Number: +82-70-4290-9046
- Fax: +82-504-845-0217

1.2 Official Correspondent

- Name: Milly (Consultant / KMC, Inc.)
- Address: Room no. 1709, 123, Digital-ro 26-gil, Guro-gu, Seoul, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: milly@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name

: EdgeFlow UH10

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: 21CFR 892.1560, 21CFR892.1570, 21CFR892.2050

2.6 Device Class: Class II

2.7 Classification Panel: Radiology

3. PREDICATE DEVICE

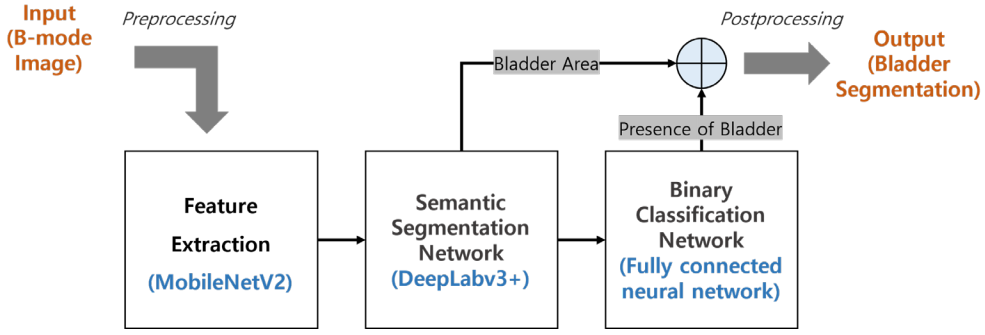
- Primary Predicate Device: BladderScan® PRIME PLUS system (K172356)
- Reference Device: Butterfly Auto 3D Bladder Volume Tool (K200980)

4. SUBJECT DEVICE DESCRIPTION

This device is an ultrasound system that measures urinary bladder volume noninvasively using ultrasound. The system consists of a handheld unit (console) with a 3.2inch touchscreen display and a permanently attached probe. The system calculates the bladder volume based on ultrasound images using the probe. The images and the bladder volume are displayed on the screen. The results of the exam are automatically saved and saved exams are managed on the screen. Data can be exported to a standard PC using a wired USB export or Wi-Fi communications.

The system includes a rechargeable lithium-ion battery. The battery can be charged in the system directly connecting a USB cable with a power adapter. Also, a cradle is available for charging the battery or printing the results.

The deep learning model employed in EdgeFlow UH10 comprises three components: feature extraction, binary classification, and semantic segmentation networks. B-mode ultrasound images undergo classification in the network to determine the presence of the bladder, while the segmentation network is responsible for delineating the bladder area. Live B-mode ultrasound images are acquired once the scan button is pressed to start scanning. The output of the deep learning model manifests as the bladder contours displayed as green lines in the ultrasound images, and the bladder volume is subsequently calculated based on these lines when the scan button is pressed.



All data used for training and test dataset were collected under a clinical trial approved by Institutional Review Board with training data being independent from the test data.

- Sample Size

Item	Training Data	Test Data
Classification Network	9,422	3,711
Segmentation Network	7,115	1,528

Bladder volume, which is the measurement output of the subject device, is reflected by the size and shape of the bladder. The size of the bladder is a result of urine accumulation in the bladder. However, bladder shape can be influenced by various factors, including pelvic structures, capacity, and bladder contents, which implies it varies from person to person and changes time to time within the same person. There is no specific relationship between bladder shape and race proven by sufficient clinical studies. Thus, demographics are only collected as auxiliary references in data collection.

Since the subject device, EdgeFlow UH10, is intended to measure bladder volume or residual urine volume, the data acquired by the target device (EdgeFlow UH10) are expected to show an imbalance between the presence of bladder and the case of bladder absence. Thus, the PR AUC (Precision-Recall Area Under Curve) is considered as a secondary endpoint for the performance test of the classification network by drawing a precision-recall curve.

For data truthing, the test dataset is independently reviewed by two evaluators who have in clinical experiences. The review results are transformed into ground truths to assess the performance of two networks.

5. INDICATION FOR USE

The EdgeFlow UH10 is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively. It is intended for use in professional healthcare facilities, such as hospitals, clinics, by qualified and trained healthcare professionals. The EdgeFlow UH10 supports B-mode and harmonic imaging modes.

6. SUBSTANTIAL EQUIVALENCE

Comparison of the technical characteristics of the subject device and predicate devices is shown in the Table of Substantial Equivalence Below.

-	Subject Device	Primary Predicate Device	Reference Device
Manufacturer	Edgecare Inc.	Verathon Inc.	Butterfly Network, Inc.
Trade Name	EdgeFlow UH10	BladderScan® PRIME PLUS system	Auto 3D Bladder Volume Tool
510(k) Number	-	K172356	K200980
Product Code	IYO, ITX, QIH	IYO, ITX	IYO, ITX
Indications for Use	The EdgeFlow UH10 is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively. It is intended for use in professional healthcare facilities, such as hospitals, clinics, by qualified and trained healthcare professionals. The EdgeFlow UH10 supports B-mode and harmonic imaging modes.	The BladderScan® Prime PLUS System is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively.	The Butterfly Auto 3D Bladder Volume Tool is a software application package. It is designed to view, quantify and report results acquired on Butterfly Network ultrasound systems for noninvasive volume measurements of the bladder, to support physician diagnosis. Indicated for use in adult populations
Contraindications	It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.	The BladderScan® Prime PLUS System is not intended for fetal use or for use on pregnant patients, patients with ascites, or patients with open skin or wounds in the suprapubic region.	The Auto 3D Bladder Volume Tool is not intended for fetal or pediatric use or for use on pregnant patients, patients with ascites, or patients with open skin or wounds in the suprapubic region.
User	Physicians/Medical Professionals	Physicians/Medical Professionals	Physicians/Medical Professionals
Target Population	Male Female Pediatric patients	Male Female Pediatric patients	Male Female
Anatomical Site	Bladder	Bladder	Bladder

Technology	Neural network technology	Neural network technology	Neural network technology
Sterility	Non-sterile	Non-sterile	Non-sterile
Power Source	Battery Powered (Lithium-ion battery)	Battery Powered (Lithium-ion battery)	Battery Powered (Lithium-ion battery)
Energy Delivered	Ultrasound	Ultrasound	Ultrasound
Measurement Accuracy	0-100mL = ±7.5mL 100-999 mL = ±7.5%	0-100mL = ±7.5mL 100-999 mL = ±7.5%	0-100mL = ±7.5mL 100-999 mL = ±7.5%
Measurement Range	0 to 999 mL	0 to 999 mL	0 to 740 mL
Automatically Calculating Function	Yes	Yes	Yes
2D/3D Image	2D	2D	3D
Mode of operation	B-mode	B-mode	B-mode
Transducer Type	Electronic Sector Scanning (Phased Array)	Mechanical Sector Probe	Electronic Sector Scanning (Phased Array)
Sector Angle	120 degrees	120 degrees	100 degrees
Number of Scan Planes	2	12	25
Portable	Yes	Yes	Yes
Display	LCD	LCD	LCD
Live Scan Image	Yes	Yes	Yes
Touch Screen	Yes	Yes	Yes
Calibration	No Calibration recommended	No Calibration recommended	No Calibration recommended
Data Connections	USB, Wireless (to PC)	USB, SD card	Wireless (to Mobile App, Cloud)
Accessories	Cradle Power Adapter USB Cable Thermal Paper	Printer, battery battery charger power cord mobile cart	Printer, battery battery charger power cord mobile cart
FDA Ultrasound Track	Track 3	Track 1	Track 3

The subject devices are substantially equivalent to the predicate and reference devices with respect to indications for use, technology and construction. The differences between the predicate devices and the subject devices are minor and any risks have been mitigated through testing. The difference does not raise new safety or effectiveness concerns for the provided intended use.

7. NON-CLINICAL DATA

As part of demonstrating substantial equivalence of the EdgeFlow UH10 to the predicate device and reference device, Edgecare Inc. conducted performance testing on the subject devices. Although there are slightly different points such as technical parts (data connection type, accessories, ultrasound track), it does not impact the ability to determine substantial equivalence of the subject devices because the substantial equivalence of performance for EdgeFlow UH10 is demonstrated by the following verification and validation data to demonstrate the safety and performance effectiveness.

- Biocompatibility

  The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were established in accordance with ISO 10993-1 and FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

  Biological Safety Assessment was prepared by using test report and others in accordance with ISO 10993-5, 10, 23

- Electrical Safety and EMC

  The electrical safety tests were performed to protect patients from undue risks arise from any hazards associated with final device. The tests were performed in accordance with the following standards.

No.	Test Items	Standards
1	General requirement for basic safety and essential performance	IEC 60601-1:2005+A1:2012
2	General requirement for safety – Electromagnetic disturbances	IEC 60601-1-2:2014/AMD1:2020

· Wireless

The following tests were performed to assess effectiveness of software of the device. The test was performed in accordance with following standards.

No.	Test Items	Standards
1	Wireless Coexistence	• ANSI IEEE C63.27-2017
2	Wi-Fi Performance Test	• In house hold

· Software

The following tests were performed to assess effectiveness of software of the device. The test was performed in accordance with following standards.

No.	Test Items	Standards
1	General requirement for safety – Programmable electrical medical systems (PEMS)	• IEC 62304:2006/A1:2015 • FDA Guidance ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices") • FDA Guidance ("Off-the-Shelf Software Use in Medical Devices")
2	Cybersecurity Test	• AAMI/UL 29001-:2017 • IEC 81001-5-1:2021 • FDA Guidance ("Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions")

· Performance Test

The following tests were performed to assess effectiveness of the product performance including characteristic properties.

No.	Test Items	Standards
1	Acoustic Output	IEC 60601-2-37:2007/AMD1:2015
2	Measurement Accuracy of Bladder Volume	Manufacturing SOP
3	Deep Neural Network Performance	Manufacturing SOP

The performance of the deep neural network was validated with a patient's dataset. Demographics are only collected as auxiliary references in data collection. All data used for training and test datasets were collected under a clinical trial approved by Yonsei University Institutional Review Board in Severance Hospital (IRB No: 1-2022-0076). Subject's demographics are described below:

Demographics of the clinical trial (Total number of subjects: 90)

Gender	Male	34 (37.78%)
	Female	56 (62.22%)
Ages	Less than 19	1 (1.11%)
	19 or more	89 (98.89%)
BMI	Maximum	36.36
	Minimum	17.41
	Average	24.34
	Variance	10.78

A total of 1,528 images were used for Segmentation, and 3,711 images were used for Classification in the ultrasound images of patients.

As information on the protocol used for testing the algorithm:

- Classification Network:
  - Input a test dataset into the deep learning model to generate the outputs of the classification network.
  - Compare the outputs (bladder presence, bladder absence) from the model's classification network with the ground truths.
  - Evaluate the performance of the classification network with 95% confidence intervals using the test criteria for the primary endpoint (F1 score: ≥0.90) and secondary endpoint (PR AUC: ≥0.95).
- Segmentation Network:
  - Input a test dataset into the deep learning model to generate the outputs of the segmentation network.
  - Compare the outputs generated from the model's segmentation network with the ground truths.
  - Evaluate the performance of the segmentation network with 95% confidence intervals using the test criteria for the primary endpoint (Dice Score: ≥0.89).

The accuracy of the classification and segmentation networks were measured respectively with the test dataset. The test criteria of classification accuracy and segmentation accuracy were both satisfied with an F1 score of 0.979 (95% CI 0.974–0.984), and a Dice score of 0.896 (95% CI 0.890–0.901). In conclusion, the deep learning model of EdgeFlow UH10 satisfies performance criteria established by Edgecare Inc.

The non-clinical overall data results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

8. CONCLUSION

The comparison between the subject devices and the predicate devices shows that the general information, some technical and material information are the same. Although there are some differences, the performance test reports are supported to the substantial equivalence of the subject device, the performance test reports are provided to demonstrate substantial equivalence of the subject devices. Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject devices are substantially equivalent to the predicate devices.