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

April 24, 2026

Re: K252337
Trade/Device Name: EdgeFlow Gel Pad
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: MUI
Dated: March 25, 2026
Received: March 25, 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: 2026.04.24 10:21:54 -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)*
K252337

Device Name
EdgeFlow Gel Pad

Indications for Use *(Describe)*
The EdgeFlow Gel Pad is a non-sterile, single-use accessory intended for use exclusively with the EdgeFlow UW20 wearable bladder scanner. The device provides acoustic coupling between the ultrasound transducer and the patient's intact abdominal skin during bladder ultrasound procedures, enabling transmission of ultrasound signals required for bladder imaging and bladder volume measurement. It is intended for use in professional healthcare facilities, such as hospitals and clinics, by qualified and trained healthcare professionals.

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:

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"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

(K252337)

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

Date: April 22, 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 Device Name: EdgeFlow Gel Pad

2.2 Model Name: 00274

2.3 Common Name: Ultrasound Coupling Media

2.4 Classification Name: Media, Coupling, Ultrasound

2.5 Product Code: MUI

2.6 Classification Regulation: 21 CFR 892.1570

2.7 Device Class: Class II

2.8 Classification Panel: Radiology

3. Predicate Device

- Primary Predicate Device: SOLID GEL PAD (K131905), BLUEMTECH
- Reference Device: AQUASONIC 100 Ultrasound Gel (K802146), PARKER LABORATORIES

4. Subject Device Description

The EdgeFlow Gel Pad is a single-use, non-sterile gel pad composed of solid silicone elastomer. The device is intended to provide acoustic coupling between the ultrasound transducer of the EdgeFlow UW20 wearable bladder scanner and the patient's intact skin. The device is supplied as a silicone gel pad protected by two removable release films (blue and transparent) and packaged in a sealed pouch. The release films are provided only to protect the gel surface during storage and handling and are removed prior to clinical use.

5. Indications for Use

The EdgeFlow Gel Pad is a non-sterile, single-use accessory intended for use exclusively with the EdgeFlow UW20 wearable bladder scanner. The device provides acoustic coupling between the ultrasound transducer and the patient's intact abdominal skin during bladder ultrasound procedures, enabling transmission of ultrasound signals required for bladder imaging and bladder volume measurement. It is intended for use in professional healthcare facilities, such as hospitals and clinics, by qualified and trained healthcare professionals.

6. Substantial Equivalence

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

	Subject Device	**Primary Predicate**	**Reference Predicate**	**SE Decision**
510(K) Number	-	K131905	K802146	-
Manufacturer	Edgecare Inc.	BLUEMTECH	PARKER LABORATORIES, INC.	-
Trade Name	EdgeFlow Gel Pad	SOLID GEL PAD	AQUASONIC 100 ULTRASOUND TRANS. GEL	-
Product code	MUI	MUI	IYO	-
Classification	Class II	Class II	-	-

Intended Use	The EdgeFlow Gel Pad is a non-sterile, single-use accessory intended for use exclusively with the EdgeFlow UW20 wearable bladder scanner. The device provides acoustic coupling between the ultrasound transducer and the patient's intact abdominal skin during bladder ultrasound procedures, enabling transmission of ultrasound signals required for bladder imaging and bladder volume measurement. It is intended for use in professional healthcare facilities, such as hospitals and clinics, by qualified and trained healthcare professionals.	Non-sterile ultrasound couplant for use with medical diagnostic ultrasound. It is intended to be used during non-invasive medical diagnostic ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gel is intended for use in all diagnostic ultrasound procedures which require ultrasound coupling gel or liquid or fluid.	Parker Laboratories Ultrasound Gel can be used on intact, unbroken skin and on all patients in facilities where cross contamination is of minimal concern. Discard empty dispenser after use. Refill containers and refillable dispensers (product numbers 01-50, 03-50 and 03-54) are for use on low-risk patients and procedures in non-acute care facilities. Follow the enclosed instructions for use or your facility's protocol, if it is different.	-
Device Form	Solid Silicone Gel Pad	Solid Gel Pad	Liquid Type	Similar to primary predicate
Single Use	Yes	Yes	Yes	Same
Sterilization	Non-sterile	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993-5, -10 tested	ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-5:2009 ISO 10993-10:2010	Same
Reusability	No (single use only)	No (single use only)	No (single use only)	Same
Packaging	Individually sealed pouches to maintain cleanliness	Individually sealed pouches to maintain cleanliness	Tube type	Same to primary predicate

Shelf Life	Supported by accelerated aging test (17 months)	Manufacturer-claimed shelf life	Manufacturer-claimed shelf life	-
Application Method	Applied as a patch between probe and skin	Applied as a patch between probe and skin	Liquid gel applied directly to skin	Same to primary predicate

Technological Differences:

The primary difference is the base material composition (silicone vs. aqueous gel). However, this difference does not raise new questions of safety or effectiveness because both materials provide equivalent acoustic coupling, meet the same biocompatibility standards, and demonstrate similar imaging performance.

7. Non-clinical and Clinical Performance Data

Bench Performance Testing

Bench testing was conducted to evaluate the performance of the EdgeFlow Gel Pad in comparison with predicate ultrasound coupling media. Testing included axial and lateral distance measurement accuracy using a multi-purpose ultrasound phantom and bladder volume measurement accuracy using a bladder phantom. The predefined acceptance criteria were axial distance accuracy of ≤ 1 mm, lateral distance accuracy of ≤ 1 mm, and bladder volume measurement accuracy of ≤ 7.5%. The test results demonstrated that the EdgeFlow Gel Pad provided comparable acoustic coupling and imaging performance relative to the predicate devices.

Acoustic and Physical Characterization

Acoustic and physical characterization was performed as part of the shelf-life verification program. The evaluated parameters included sound velocity, acoustic impedance, and attenuation coefficient. These characteristics were assessed to confirm that the gel pad maintains appropriate ultrasound transmission properties throughout its labeled shelf life.

Acoustic and Physical Properties

Acoustic characterization was performed to verify ultrasound transmission properties and stability over the labeled shelf life.

Test Item	Results
Density	995.60 kg/m^3
Sound Velocity	970.00 m/s
Acoustic Impedance	0.97 MRayl
Attenuation Coefficient	0.080 dB/mm/MHz
Hardness (Shore A)	55.4 (average)
Adhesive Strength	4.40 N (average)
Release Film Peeling Force	0.027 N/24mm (average)

Biocompatibility

Biocompatibility testing was conducted in accordance with ISO 10993-5 and ISO 10993-10 for a skin-contacting device intended for contact of up to 24 hours. The device was evaluated for cytotoxicity, sensitization, and irritation. The results support that the EdgeFlow Gel Pad is biocompatible for its intended use.

Packaging and Microbiological Testing

Packaging and microbiological evaluations were performed as part of the real-time shelf-life verification program. Testing included bioburden evaluation, dye penetration testing in accordance with ASTM F1929, and seal strength testing in accordance with ASTM F88/F88M. These evaluations were conducted to confirm maintenance of packaging integrity and freedom from microbial contamination over the labeled shelf life. Dye penetration testing showed no evidence of package seal leakage, seal strength testing met the predefined acceptance criteria, and bioburden testing supported maintenance of acceptable bioburden levels.

Shelf Life

Real-time stability testing was conducted to evaluate mechanical, acoustic, imaging, microbiological, and packaging integrity characteristics over time. These data support a shelf life of 17 months for the EdgeFlow Gel Pad.

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 system with the designated EdgeFlow Gel Pad. Ten adult subjects participated in the study. A total of 1,454 ultrasound images were evaluated, and 1,414 images maintained valid acoustic coupling, resulting in an overall acoustic coupling retention ratio of 97.24%, which exceeded the predefined acceptance criterion of 80%. Self-reported scores for skin discomfort, sweat, and gel pad slippage remained minimal on a 5-point scale, and no adverse events or early device removals were reported. These results support that the designated gel pad can maintain stable acoustic coupling during the intended 24-hour wear period when used with the EdgeFlow UW20 wearable bladder scanner under representative clinical use conditions.

8. Conclusion

The EdgeFlow Gel Pad and the predicate device have similar intended use and technological characteristics. Non-clinical testing demonstrates that the EdgeFlow Gel Pad is biocompatible, maintains functional performance over its intended shelf life, and is safe and effective for use as intended. These results support a finding of substantial equivalence. Therefore, Edgecare Inc. considers the subject device to be as safe and effective as, and substantially equivalent to, the primary predicate device.